

Exhibit 2

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN PRODUCTS
LIABILITY LITIGATION

Hon. Robert B. Kugler

Hon. Joel Schneider

Civil No. 1:19-md-2875-RBK-JS

**MYLAN’S OBJECTIONS TO PLAINTIFFS’ FIRST SET OF REQUESTS FOR
PRODUCTION OF DOCUMENTS TO ALL API AND FINISHED-DOSE
MANUFACTURING DEFENDANTS**

In accordance with Case Management Order No. 10 (Dkt. 141) and Case Management Order No. 12 (Dkt. 185), Defendant Mylan Pharmaceuticals Inc. (MPI or “Mylan”) serves these Objections to Plaintiffs’ First Set of Requests for Production of Documents to All API and Finished-Dose Manufacturing Defendants (“Requests”).

MYLAN’S PRELIMINARY STATEMENT

Mylan Laboratories Ltd. (MLL) is an Indian company with its principal place of business in India. MLL manufactures valsartan API pursuant to Drug Master File No. 018253 (DMF), as well as two finished-dose products: amlodipine and valsartan tablets (ANDA 090483) and valsartan tablets, USP (ANDA 090866). MPI is a West Virginia corporation with its principal place of business in West Virginia. MPI is a finished-dose manufacturer of valsartan and hydrochlorothiazide tablets, USP (ANDA 078020) and a distributor of the three aforementioned finished-dose valsartan-containing medications (VCMs). MLL and MPI are both indirectly wholly owned subsidiaries of Mylan N.V., which is a publicly traded, Dutch holding company that plays no role in the manufacture, distribution, and sale of VCMs.

MLL has manufactured valsartan API at two facilities, identified as Unit 3 and Unit 8. Their addresses and Establishment Registration Numbers are set forth below.

UNIT 3	UNIT 8
Plot Nos. 35, 36, 38–40, 49–51 Phase IV, IDA, Jeedimetla Hyderabad – 500055 Telangana, India Registration (FEI) Number: 3003937580	G. Chodavaram Poosapatirega Mandal Vizianagaram District – 535204 Andhra Pradesh, India Registration (FEI) Number: 3002785310

By way of further clarification, in November 2017, the DMF was amended to remove Unit 3 as a manufacturing site for valsartan API, meaning that, at present, all valsartan API manufactured by MLL is produced at Unit 8.

MPI holds a total of four ANDAs concerning VCMs.

1. ANDA 090866 (generic to Diovan), approved January 5, 2015
2. ANDA 078020 (generic to Diovan HCTZ), approved September 21, 2012
3. ANDA 090483 (generic to Exforge), approved March 30, 2015
4. ANDA 204743 (generic to Exforge HCTZ), approval pending

Valsartan-containing finished dose products are manufactured at three facilities: (i) Nashik, India (FEI No. 3005587313); (ii) Aurangabad, India (FEI No. 3008316970); and (iii) Morgantown, West Virginia (FEI No. 1110315).

On November 20, 2018, MPI announced the voluntary recall of 15 lots of MLL-sourced VCMs manufactured for the United States market due to the potential presence of N-Nitrosodiethylamine (NDEA). MPI's voluntary recall was expanded on December 4, 2018, to include all VCMs within expiry. Neither of these recalls related to the potential presence of N-Nitrosodimethylamine (NDMA), N-Nitroso-N-methyl-4-aminobutyric acid (NMBA), or any other alleged contaminant.

With the exception of ANDA 204743, which remains pending before the FDA, Mylan has already produced as part of the "core discovery" process the aforementioned ANDA files, MLL's DMF for valsartan API, and relevant FDA correspondence relating to the recall of VCMs, the related investigation, and efforts to ensure NDEA and other nitrosamines are not present on a going-forward basis.

GENERAL OBJECTIONS AND RESERVATION OF RIGHTS

The following General Objections apply to all specifications of the Requests. Each General Objection is hereby incorporated in the response to each individually numbered Request as if fully set forth therein.

1. Mylan objects to each Definition and Request to the extent that it calls for the disclosure of information protected by any privilege or protection, including without limitation the attorney-client privilege, the work-product doctrine, community of interest privilege, joint-defense privilege, the insurer-insured privilege, the privilege afforded financial records, the right of privacy of any person or entity, and any other available and valid grounds for withholding

information from disclosure. Nothing contained in these objections and responses is intended to be, or in any way constitutes, a waiver of any applicable privilege or immunity. Any inadvertent production of information protected by the attorney–client privilege, prepared in anticipation of litigation or trial, or otherwise protected or immune from discovery shall not constitute a waiver of any privilege nor of any other basis for objecting to the use of such material or its subject matter. Mylan expressly reserves the right to object to the use or introduction of such information.

2. Mylan objects to each Definition and Request to the extent it is vague, ambiguous, overbroad, and/or unduly burdensome.

3. Mylan objects to each Definition and Request to the extent it is not reasonably limited as to time, scope, and/or geographical location. This litigation relates to the sale, purchase, and use of VCMs in the United States. Mylan did not market VCMs in United States until September 21, 2012, and, as noted, Mylan has already produced the ANDA files and DMF relating to the products allegedly at issue. Accordingly, Mylan objects to the extent Plaintiffs seek information predating September 21, 2012 or relating to markets, jurisdictions, or laws other than those of the United States.

4. Mylan objects to each Definition and Request to the extent it attempts to impose on Mylan burdens and obligations beyond those required by the Federal Rules of Civil Procedure, the local rules of the District of New Jersey, or any other applicable rule or law.

5. Mylan objects to each Definition and Request to the extent it seeks documents or information not relevant to the subject matter of the litigation and/or disproportionate to the needs of this case, including documents unrelated to VCMs. Mylan further objects to each Request to the extent it seeks information whose relevance is outweighed by the burden imposed on Mylan in having to search for and provide such information.

6. Mylan objects to each Request to the extent it is duplicative of other Requests.

7. Mylan objects to each Request to the extent it seeks documents that are not within Mylan’s possession, custody, or control including, but not limited to, documents that are in the physical custody of another person or entity. Mylan further objects to each Request to the extent that it seeks documents—such as the ANDA files, DMF, and other materials produced as part of the core discovery process—that are already in Plaintiffs’ possession, custody, or control or that are in the public domain and accessible to all parties.

8. Mylan objects to each Request to the extent it seeks documents or information for which the consent of any third party must be obtained prior to its disclosure or production.

9. Mylan objects to each Request and Definition to the extent it requires Mylan to create documents not currently in existence and imposes a burden not required under the Federal Rules of Civil Procedure or the local rules of the District of New Jersey. Mylan will comply with those rules and, in responding to Plaintiffs' requests, will conduct a reasonable search for and produce nonprivileged documents within its possession, custody, and control.

10. Mylan objects to each Request and Definition to the extent it requires a search of archived files (including computer back-up tapes) that would be unduly burdensome and not reasonably likely to yield non-duplicative, responsive material or information.

11. Mylan objects to each Request to the extent it purports to require a search or production of files from Mylan's in-house or outside counsel.

12. Mylan objects to each Request to the extent it seeks information or documents that contain confidential financial, trade secret, competitive, business, or other proprietary information of Mylan, its employees, and/or third parties. Mylan will produce such documents pursuant to the terms of the Confidentiality and Protective Order (Dkt. 139) and ESI Protocol (Dkt. 127) entered in the above-captioned litigation.

13. Mylan's responses to the Requests shall not be construed in any way as an admission that any Definition provided by Plaintiffs is either factually or legally binding upon Mylan. Mylan further rejects the suggestions or conclusions implicit in the Requests. Nor shall Mylan's Objections herein be construed as a waiver of any of Mylan's objections to the use of any response for any purpose, in these actions or any other action, including but not limited to, objections regarding relevance, discoverability, and admissibility of documents.

14. Mylan objects to the terms "policy," "policies," "practices," or "procedures" (as used in, for example, Request Nos. 5, 16, 89, and 96) as overbroad, unduly burdensome, vague and ambiguous, in that they could be interpreted to mean something other than a formal written policy, practice, or procedure. For purposes of these Objections, Mylan will interpret and use "policy," "policies," "practices," and "procedures" to mean a final, formal written policy, practice, or procedure.

15. Mylan objects to the terms "all," "any," and "each" (as used in, for example, Request Nos. 5–16, 18–57, 59–92, 94–107, and 109–22) as vague, ambiguous, overbroad, and/or

unduly burdensome, and failing to comply with the requirements of Federal Rule of Civil Procedure 34(b)(1)(A) to “describe with reasonable particularity each item or category of items to be inspected,” as it would require Mylan to conduct searches broader than a reasonable and diligent search of reasonably accessible files (including electronic files) where responsive documents reasonably would be expected to be found. In producing documents responsive to the Requests, Mylan will conduct a reasonable search for responsive documents from agreed-upon custodians and/or depending on the nature of each individual Request, from databases where responsive documents reasonably would be expected to be found.

16. Mylan objects to Plaintiffs’ Definition of the term “Active Pharmaceutical Ingredient” or “API” as overbroad and unduly burdensome in that it is broader than the definition of Active Pharmaceutical Ingredient provided by the FDA and is not limited to valsartan. Mylan further objects to this Definition as vague and ambiguous in that it includes “any substance or mixture of substances that become the active ingredient of a drug product.” For purposes of these Objections, Mylan will interpret and use “Active Pharmaceutical Ingredient” or “API” to have the definition provided by the FDA: “[A]ny substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance.” 21 C.F.R. § 207.1; *see also* 21 C.F.R. § 314.3. Further, Mylan will interpret and use “Active Pharmaceutical Ingredient” or “API” to mean Valsartan API.

17. Mylan objects to the Definition of “API Manufacturer” as overbroad, unduly burdensome, vague, and ambiguous, in that it would encompass numerous unidentified entities that manufacture any active pharmaceutical ingredient. For purposes of these Objections, Mylan will interpret and use “API Manufacturer” to mean any entity that manufactures the Valsartan API.

18. Mylan objects to the Definition of “Finished Dose Manufacturer” as overbroad, unduly burdensome, vague, and ambiguous in that it would encompass numerous unidentified entities that manufacture any finished dosage form. Mylan further objects to this Definition as overbroad and unduly burdensome in that it encompasses activities beyond those of manufacturing a finished dosage form. For purposes of these Objections, Mylan will interpret and use “Finished Dose Manufacturer” to mean any entity that manufactures VCMs in a finished dosage form—e.g., tablet, capsule, or solution.

19. Mylan objects to the Definition of “Communication(s)” as overbroad, unduly burdensome, vague, and ambiguous in that it purports to impose burdens on Mylan beyond those authorized by Rule 34 of the Federal Rules of Civil Procedure.

20. Mylan objects to the Definition of “Documents” as overbroad and unduly burdensome in that it seeks documents outside of Mylan’s custody and control. Mylan further objects to this definition as it purports to impose burdens on Mylan beyond those authorized by Rule 34 of the Federal Rules of Civil Procedure and seeks to expand the definition of ESI beyond the scope of set forth in Case Management Order No. 8, Electronic Discovery Protocol.

21. Mylan objects to the Definition of “Relevant Time Period” as overbroad, unduly burdensome, and not proportional in that it would require production of documents unrelated to the events at issue in this case. For reasons stated above and for the purposes of these Objections, Mylan will interpret and use “Relevant Time Period” to mean September 21, 2012 to present.

22. Mylan objects to the Definition of “Regulatory and Regulatory Authority” as overbroad, unduly burdensome, vague, and ambiguous in that it would encompass any regulatory agency around the world. Because this litigation involves the purchase or use of VCMs in United States, for the purposes of these Objections, Mylan will interpret and use “Regulatory and Regulatory Authority” to mean the FDA.

23. Mylan objects to the Definition of “TPP” as overbroad, unduly burdensome, vague, and ambiguous. For purposes of these Objections, Mylan will interpret and use “TPP” to mean health care providers, plans, and providers as those terms are defined in the Third Party Payor Fact Sheet to be used in this litigation.

24. Mylan objects to the Definition of “Valsartan” as overbroad, unduly burdensome, vague, and ambiguous in that it encompasses both Valsartan API and finished dosage forms. For the purposes of these Objections, Mylan will distinguish between “Valsartan API” and “Valsartan” (finished-dose VCMs).

25. Mylan objects to the definition of “You,” “Your,” or “defendant” as overbroad unduly burdensome, vague, and ambiguous in that it is to be used “interchangeably” for the parties to which the requests are directed. Mylan will search for and provide information within its possession, custody, and control.

26. Mylan objects to each Request to the extent it seeks information pertaining to alleged side effects or adverse reactions associated with VCMs other than those of the character

allegedly experienced by Plaintiffs, on the grounds that such information is not relevant to this litigation and not reasonably calculated to lead to the discovery of admissible evidence.

27. Mylan objects to each Request to the extent it seeks to impose an independent reporting obligation on the part of Mylan's counsel.

28. Mylan reserves the right to supplement or amend these Objections.

29. Mylan incorporates these General Objections into each of the following Specific Objections, which are made subject to, and without waiver of, these General Objections and limitations.

DEFINITIONS FOR PURPOSES OF MYLAN'S OBJECTIONS

1. "Actions" shall refer to those suits centralized for pretrial proceedings in MDL No. 2875 pending in the U.S. District Court for the District of New Jersey, Case No. 1:19-md-2875.

2. "Active Pharmaceutical Ingredient" ("API") will be interpreted consistent with the definition used by the FDA: "[A]ny substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance." 21 C.F.R. § 207.1; *see also* 21 C.F.R. § 314.3.

3. "API Manufacturer" means an entity that manufactures Valsartan API.

4. "Communication(s)" shall be interpreted in a manner consistent with the ESI Protocol (Dkt. 127) entered in this litigation.

5. "Finished Dose Manufacturer" means an entity that manufactures finished-dose valsartan-containing medications.

6. "Regulatory and Regulatory Authority" refers to the United States FDA.

7. "Relevant Time Period" means September 21, 2012 to present

8. "Valsartan" will be interpreted to mean valsartan-containing medications in a finished dose form.

SPECIFIC OBJECTIONS TO REQUESTS FOR PRODUCTION OF DOCUMENTS

I. CORPORATE ORGANIZATION

REQUEST NO. 1: *Produce organizational charts setting forth the corporate organization for each named defendant, from January 2010 to the present as follows:*

- a. General corporate organizational charts for each defendant, including any affiliated entities involved in the manufacture, testing, distribution, or sale of valsartan;*
- b. Medical affairs/clinical affairs department, or the equivalent;*
- c. Quality assurance department, or the equivalent;*
- d. Manufacturing department, including any departments involved in the manufacturing process for valsartan;*
- e. Procurement Department;*
- f. Sales department;*
- g. Marketing department;*
- h. Research and development department;*
- i. Department(s) responsible for designing, funding, or supervising clinical trials (including all Phase I, II, III, and IV);*
- j. Regulatory department;*
- k. Department responsible for epidemiology and/or statistical analysis;*
- l. Professional education department;*
- m. Department(s) responsible for establishing or maintaining relationships involving valsartan, with any other defendant named in this MDL.*

RESPONSE TO REQUEST NO. 1: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to those employees responsible for the design, manufacture, distribution, and recall of Valsartan and Valsartan API. Moreover, the parties have engaged in a series of meet-and-confers to allow Plaintiffs to identify those persons most likely to have knowledge regarding the aforementioned subject matters and, therefore, this Request is duplicative. (*See* Dkt. 185, Case Management Order No. 12.) Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Rule 34 of the Federal Rules of Civil Procedure. Mylan further objects to this Request on the grounds that the phrases "establishing or maintaining relationships involving valsartan" and "procurement department" are vague and ambiguous. Notwithstanding the above, and subject to the objections asserted herein, Mylan states that it does not maintain organizational charts in the ordinary course of business. Nonetheless, Mylan reaffirms its commitment to work through informal discovery methods and in good faith with Plaintiffs' counsel to prepare acceptable and appropriate lists of ESI custodians. (*See* Dkt. 258.) In that regard, Mylan refers Plaintiffs to the materials produced at

MYLAN-MDL2875-00030973–30974, which reflect the organization of those departments within MLL responsible for the manufacture and quality of Valsartan API as they existed in 2019.

REQUEST NO. 2: *From 2010 to the present, produce documents sufficient to demonstrate:*

- a. All corporate officers;*
- b. All members of the Board of Directors;*
- c. All persons or entities which own or owned 5% or more of defendant's common stock; and [sic]*

RESPONSE TO REQUEST NO. 2: Mylan objects on the basis that a Request seeking documents “sufficient” for a particular purpose is vague, ambiguous, and subject to numerous interpretations and, therefore, violative of Plaintiffs’ obligation to describe with reasonable particularity each item or category of items to be produced. Mylan objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks information regarding individuals and entities who are not responsible for the design, manufacture, distribution, and recall of Valsartan and who have no bearing in this product-liability litigation, which centers upon Plaintiffs’ allegation that an impurity arose during the manufacture of Valsartan API. Mylan further objects to the extent this Request seeks documents predating September 21, 2012. Mylan also objects to this Request to the extent it seeks information that is publicly available or available from another source that is more convenient. Mylan incorporates, by reference, the Rule 7.1 corporate disclosure statements filed before the Judicial Panel on Multidistrict Litigation and the District Court for the District of New Jersey.

REQUEST NO. 3: *To the extent you conduct business relating to valsartan with any other defendant in the above-captioned MDL, produce documents sufficient to demonstrate the nature, extent, and length of this business relationship.*

RESPONSE TO REQUEST NO. 3: Mylan objects on the basis that a Request seeking documents “sufficient” for a particular purpose is vague, ambiguous, and subject to numerous interpretations and, therefore, violative of Plaintiffs’ obligation to describe with reasonable particularity each item or category of items to be produced. Mylan objects on the same basis with regard to the phrases “conduct business” and “business relationship,” which are undefined and ambiguous as phrased. Mylan further objects to this Request as irrelevant, duplicative of subsequent requests, overbroad, unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to documents relating to the manufacture of Valsartan API or the

purchase and use of Valsartan. As such, the Request seeks production of a wide swath of immaterial information wholly unrelated to the issues in this case, which centers upon Plaintiffs' allegation that an impurity arose during the manufacture of Valsartan API. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. By way of further answer, Mylan states as follows: As plaintiffs are aware, over 40 entities (and counting) have been named as defendants in this MDL, collectively representing every link in the chain of distribution of Valsartan. Suffice it to say, the relationship between these entities is contractual in nature. Taken literally, this Request would require the production of each and every contract or written agreement entered into between the dozens of defendants named in this MDL—an obvious absurdity. While Mylan is willing to engage in a meet-and-confer with plaintiffs to narrow and more properly define the scope of this Request, as written it clearly is beyond the scope of permissible discovery.

II. RELEVANT CUSTODIANS

REQUEST NO. 4: *Produce documents sufficient to identify the corporate employees or third parties responsible for or involved in the (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, and (16) communications with private individuals or entities, with regard to valsartan, and/or the ingredients thereof.*

RESPONSE TO REQUEST NO. 4: Mylan objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek “documents sufficient to identify” corporate employees and third parties and therefore does not identify specific documents with reasonable particularity. Mylan further objects that this on the grounds that this Request is not proportional to the needs of each case, as the Court has already set forth a process for the parties to identify relevant custodians for the API and finished dose manufacturer Defendants in Case Management Order No. 12 (Dkt 185). Mylan objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that the sixteen (16) topics identified are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks information regarding

job functions including risk assessment, formulation, distribution, packaging, evaluation, sale, and marketing that are not related to the NDMA and NDEA impurities at issue in the Actions. Mylan accordingly objects to this Request as it seeks documents unrelated to Valsartan or the Valsartan recall and which are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions. Even if limited to documents related to Valsartan or the Valsartan recall, the Request is overbroad, unduly burdensome, and not proportional to the needs of the Actions in that seeking documents "sufficient" to identify all employees or third parties "involved in" the various activities articulated is beyond a focused request and impermissibly broad. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it would impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Moreover, Mylan has produced thousands of pages of core discovery documents from which Plaintiffs can identify most, if not all, of the individuals primarily involved in the various activities listed in the Request, and Defendant refers Plaintiffs to such documents. Notwithstanding the above, and subject to the objections asserted herein, Mylan reaffirms its commitment to work through informal discovery methods and in good faith with Plaintiffs' counsel to prepare acceptable and appropriate lists of ESI custodians. (See Dkt. 258.) As part of that process, Mylan refers Plaintiffs to the materials produced at MYLAN-MDL2875-00030973–30974, which reflect the organization of those departments within MLL responsible for the manufacture and quality of Valsartan API as they existed in 2019.

III. POLICIES AND PROCEDURES

REQUEST NO. 5: *Produce all documents setting forth all draft and final versions of policies, procedures, standard operating procedures, or protocols for or relevant to the (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, and (16) communications with private individuals or entities, with regard to valsartan, and/or the ingredients thereof. In addition, provide all indexes or lists of the requested documents.*

RESPONSE TO REQUEST NO. 5: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions insofar as it demands production of “all” documents of a particular type; it is unlimited in time; it is unlimited in geography; and it is not limited to the alleged defect (presence of NDEA) or risk (cancer) at issue in the Actions. Mylan further objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that the sixteen (16) topics identified are not limited to Valsartan or the Valsartan recall and, to the extent they seek communications with regulatory agencies, they are not limited to domestic regulatory agencies. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent they include communications with foreign regulatory agencies and “private individuals” unrelated to the recalls or related issues. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. The burden is particularly glaring insofar as the Request purports to demand the production of both drafts and final versions of “all” documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record—including “indexes or lists of the requested documents”—that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request on the grounds that the terms “policies,” “procedures,” “protocols,” and “evaluation” (among others) are vague, ambiguous, and lacking in particularity. By way of further answer, Defendant states as follows: Rule 34(b)(1)(A) requires a party serving discovery to “describe with reasonable particularity each item or category of items” to be produced. This Request is tantamount to plaintiffs demanding production of “all” documents—including drafts—that are or may be “relevant” in this sprawling MDL. While Mylan is willing to engage in a meet-and-confer with plaintiffs to narrow and more properly define the scope of this Request, as written it clearly is beyond the scope of permissible discovery.

IV. AGREEMENTS

REQUEST NO. 6: *Produce all formal and informal agreements, contracts, or licenses that the answering defendant is a party to, with regard to (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, (16) communications with private individuals or entities, and (17) procurement, with regard to valsartan and/or its ingredients.*

RESPONSE TO REQUEST NO. 6: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to topics reasonably related to the issues in the Actions, and it demands the production of “all” documents fitting within seventeen (17) general categories. Mylan further objects to this Request as overbroad and unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to topics reasonably related to the alleged contamination of Valsartan API with the impurity (NDEA) at issue in the Actions and instead seeks documents related to the packaging, sale, and marketing of Valsartan and/or its ingredients, documents relating to “communications with private individuals or entities,” and documents related to any ingredients in Valsartan. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that, to the extent it seeks materials related to communications with regulatory agencies, the Request is not limited to domestic regulatory agencies. Mylan objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that the seventeen (17) topics identified are not limited to Valsartan or issues relating to the Valsartan recall. Mylan further objects to this Request on the grounds that the term “informal agreements” is vague, ambiguous, overbroad and unduly burdensome, and lacking in particularity. Mylan also objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. While Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, as written it clearly is beyond the scope of permissible discovery.

REQUEST NO. 7: *Produce all documentation, including agreements, draft agreements, memoranda, and physician expense reports, relating, referring to or embodying any attempt by defendant to retain, engage or otherwise provide financial support or item of value to any person*

with regard to proposed or actual scientific or medical study of valsartan, from January 1, 2010 to the present.

RESPONSE TO REQUEST NO. 7: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents and documents outside of the Relevant Time Period. Mylan further objects to this Request as overbroad and unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to topics reasonably related to the alleged presence of NDEA in Valsartan API. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request on the grounds that the term “financial support or item of value” is vague, ambiguous, overbroad and unduly burdensome, and lacking in particularity. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Without waiving the foregoing objections, Mylan states that, in connection with the submission and maintenance of MLL’s DMF and the ANDA files concerning the three VCMs it markets in United States, including the implementation of the aforementioned recalls and the related investigation, Mylan’s employees and, in some instances, third parties were engaged in the “scientific or medical study of valsartan.” In that regard, Mylan refers Plaintiffs to the DMF, ANDA files, and FDA correspondence produced during core discovery. Otherwise, Mylan states that it is not presently aware of any documents responsive to this Request.

REQUEST NO. 8: *Produce all documents relating, referring to or embodying any discussions, negotiations or contracts to engage any third party to represent your interests before the FDA or any regulatory authority, or any Committee or subcommittee thereof, in regard to valsartan, including, but not limited to, retainer agreements or consultant agreements.*

RESPONSE TO REQUEST NO. 8: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to domestic regulatory agencies and it requests the production of “all” documents. Mylan further objects to this Request as overbroad and unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to topics reasonably related to the alleged presence of NDEA in Valsartan

API. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Without waiving the foregoing objections, Mylan states that it is not presently aware of any documents responsive to this Request.

REQUEST NO. 9: *Produce all documents relating, referring to or embodying the retention of persons in any medical or scientific discipline to study, assess or analyze the safety of valsartan by or on behalf of any defendant, whether retained directly by any defendant or otherwise.*

RESPONSE TO REQUEST NO. 9: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents. Mylan further objects to this Request as overbroad and unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to topics reasonably related to the alleged presence of NDEA in Valsartan API. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request in that it seeks documents or information that are not known or are outside Mylan’s possession, custody or control. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine or otherwise demands the identification of experts retained in connection with pending litigation. Mylan states that it will abide by the expert-disclosure deadlines established by the Court. Without waiving the foregoing objections, Mylan states that, in connection with the submission and maintenance of MLL’s DMF and the ANDA files concerning the three VCMs it markets in United States, including the implementation of the aforementioned recalls and the related investigation, Mylan’s employees and, in some instances, third parties were engaged in the study and analysis of the safety of valsartan. In that regard, Mylan refers Plaintiffs to the DMF, ANDA files, and FDA correspondence produced during core discovery. Otherwise, Mylan states that it is not presently aware of any documents responsive to this Request.

V. INTRA-DEFENDANT COMMUNICATIONS

REQUEST NO. 10: *All communications between any of the defendants related to (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk*

assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, and (16) communications with private individuals or entities, with regard to valsartan and/or the ingredients thereof.

RESPONSE TO REQUEST NO. 10: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that the sixteen (16) topics identified are not limited to issues pertaining to the alleged presence of NDEA in Valsartan API, but instead seeks documents related to the packaging, sale, and marketing of Valsartan and/or its ingredients, documents relating to “communications with private individuals or entities,” and documents related to any ingredients in Valsartan. Without waiving the foregoing objections, Mylan states as follows: As Plaintiffs are aware, over 40 entities (and counting) have been named as defendants in this MDL, collectively representing every link in the chain of distribution of Valsartan. Suffice it to say, the relationship between these entities is contractual in nature. Taken literally, this Request would require the production of each and every contract or written agreement entered into between the dozens of defendants named in this MDL—an obvious absurdity. While Mylan is willing to engage in a meet-and-confer with plaintiffs to narrow and more properly define the scope of this Request, as written it clearly is beyond the scope of permissible discovery.

VI. ANDA AND DMF

REQUEST NO. 11: *To the extent any ANDA file for any valsartan was not produced in whole or in part during core discovery, produce the entire file, whether or not ultimately approved, beginning from the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.*

RESPONSE TO REQUEST NO. 11: Mylan objects to those parts of this Request which are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to the extent this request seeks documents and information related to ANDA files “whether or not ultimately approved” as such documents are neither relevant to any party’s claims

or defenses nor proportional to the needs of the Actions to the extent it seeks documents unrelated to products allegedly purchased or used by Plaintiffs. Without waiving the foregoing objections, Mylan states that it has already produced as part of core discovery the ANDA files for the three VCMs it markets in United States. Mylan incorporates, by reference, its Response to Request No. 115.

REQUEST NO. 12: *Produce all correspondence with the FDA concerning any ANDA for valsartan, whether or not ultimately approved, beginning from the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.*

RESPONSE TO REQUEST NO. 12: Mylan objects to those parts of this Request which are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to the extent this request seeks documents and information related to ANDA files "whether or not ultimately approved" as such documents are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents unrelated to the products allegedly purchased or used by Plaintiffs. Mylan further objects to this Request on the basis that it seeks information unrelated to the alleged presence of NDEA in VCMs which Plaintiffs allege arose during the manufacture of Valsartan API. Without waiving the foregoing objections, Mylan states that, consistent with the Court's core discovery order, it has and will continue to produce communications with FDA relating to the Valsartan recalls, the potential presence of nitrosamines in Valsartan API, related investigations, and Mylan's efforts to ensure impurities are not present on a going-forward basis. Mylan also directs Plaintiffs to the ANDA files relating to the three VCMs it markets in the United States, which were produced as part of core discovery.

REQUEST NO. 13: *Produce all documents containing the list of ingredients in valsartan, which were provided to any regulatory authority, beginning from the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.*

RESPONSE TO REQUEST NO. 13: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to domestic

regulatory agencies and it requests the production of “all” documents. Mylan further objects to this Request as vague, overbroad, and unduly burdensome, lacking in particularity, and unreasonable, as documents containing “the list of ingredients in valsartan” is not limited to the ingredients for Valsartan API, which is the process identified by Plaintiffs as the source of the alleged impurities. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks documents which were provided to “any regulatory authority” rather than the FDA. Mylan objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA and DMF files and related FDA correspondence produced during core discovery. To the extent Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 14: *Produce all documents relating to New Drug Applications filed by you relating to valsartan, beginning from the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.*

RESPONSE TO REQUEST NO. 14: Mylan objects to this Request as vague and lacking in particularity, as “New Drug Application” is a defined term which refers to a specific application, review, and approval process by the FDA that is distinct from the ANDA and DMF files also referenced in Request No. 14. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks documents related to New Drug Applications rather than the Valsartan ANDAs and DMFs at issue. Mylan objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Notwithstanding the above, Mylan states that it has not filed any New Drug Applications relating to VCMs.

REQUEST NO. 15: *Produce all complete drug master files for valsartan.*

RESPONSE TO REQUEST NO. 15: Mylan objects to those parts of this Request which are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan

objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Without waiving the foregoing objections, Mylan states that MLL's DMF for Valsartan API has already been produced in this litigation.

VII. LITIGATION AND DOCUMENT PRESERVATION

REQUEST NO. 16: *Produce all document retention or destruction policies in effect from January 1, 2010 to the present.*

RESPONSE TO REQUEST NO. 16: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and seeks documents outside the scope of the Relevant Time Period. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions.

REQUEST NO. 17: *Produce documents sufficient to show the name, case caption, attorney, and/or status of any lawsuit filed against you relating to valsartan contamination.*

RESPONSE TO REQUEST NO. 17: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek "documents sufficient to show" various aspects of lawsuits therefore does not identify specific documents with reasonable particularity. Mylan further objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request in that it seeks documents or information that are outside Mylan's possession, custody or control or pertain to litigation outside of the United States. Mylan also objects to this Request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Without waiving the foregoing objections, Mylan states that it is not aware of any lawsuits pending in United States concerning the alleged presence of NDEA in

Mylan's VCMs other than those already part of this MDL or filed by Plaintiffs' counsel involved in this MDL and, therefore, the requested information is equally accessible to Plaintiffs.

REQUEST NO. 18: *Produce all documents upon which Defendant relies to support each and every affirmative defense asserted in the Answer or which you may assert.*

RESPONSE TO REQUEST NO. 18: Mylan objects to this Request in that it is premature because discovery is ongoing and, moreover, all pleading deadlines have been stayed. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine.

VIII. MANUFACTURING

REQUEST NO. 19: *Produce all documents with regard to the manufacturing process for the active pharmaceutical ingredient in valsartan, including any modifications thereto.*

RESPONSE TO REQUEST NO. 19: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks information about all aspects of the Valsartan API manufacturing process and requests the production of “all” documents and “any modifications thereto.” Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the specific step in the Valsartan API manufacturing process that allegedly generated NDEA. Mylan further objects to this Request as vague, ambiguous, overbroad, and unduly burdensome, lacking in particularity, and unreasonable, as “all documents with regard to the [API] manufacturing process” does not identify any particular set of documents and is duplicative of many other Requests, including Requests No. 20–21 and 23–29. Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as unduly burdensome and not proportional to the needs of the Actions, in that it seeks documents and information already produced through core discovery. While Mylan is willing to engage in a meet-and-confer with plaintiffs to narrow and more properly define the scope of this Request, as written it clearly is beyond the scope of permissible discovery.

REQUEST NO. 20: *Produce all documents with regard to the machines, materials, and substances (including but not limited to new or recycled solvents, tainted or contaminated solvents) utilized in the manufacturing process for the active pharmaceutical ingredient in*

valsartan, including specifications, manuals, material safety data sheets, machine settings and calibrations, and any modifications thereto.

RESPONSE TO REQUEST NO. 20: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks information about all aspects of the API manufacturing process and requests the production of “all” documents and “any modifications thereto.” Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the machines, materials, and substances used during the specific step in the Valsartan API manufacturing process that allegedly generated NDEA. Mylan further objects to this Request as vague, overbroad, and unduly burdensome, lacking in particularity, and unreasonable, as “all documents with regard to the machines, materials, and substances” does not identify any particular set of documents and is duplicative of other Requests, including Requests No. 21 and 25. Notwithstanding the above, and subject to the objections asserted herein, While Mylan is willing to engage in a meet-and-confer with plaintiffs to narrow and more properly define the scope of this Request, as written it clearly is beyond the scope of permissible discovery.

REQUEST NO. 21: *Produce all documents (including photographs or video) with regard to any testing or inspections of the machines, materials, and substances utilized in the manufacturing process for the active pharmaceutical ingredient in valsartan.*

RESPONSE TO REQUEST NO. 21: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks information about all aspects of the API manufacturing process and requests the production of “all” documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the machines, materials, and substances used during the specific step in the Valsartan API manufacturing process that allegedly generated NDEA. Notwithstanding the above, and subject to the objections asserted herein, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it clearly is beyond the scope of permissible discovery.

REQUEST NO. 22: *Produce all documents setting forth the manufacturing/fabrication/production process for the finished drug formulation of valsartan sold by you or any of your affiliated entities, including any quality assurance and testing, and any modifications thereto.*

RESPONSE TO REQUEST NO. 22: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks information about all aspects of the finished dose manufacturing process and requests “all” documents and “any modifications thereto.” Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDEA in Valsartan. Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control or otherwise would require an unreasonable search of Mylan’s documents, in that it requests documents from “any . . . affiliated entities.” Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files produced during core discovery, which describes the process used to manufacture Mylan’s Valsartan and any modifications thereto. To the extent Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 23: *Produce all documents identifying any patented device, machine, or technology utilized in the manufacture or testing of valsartan.*

RESPONSE TO REQUEST NO. 23: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests publicly available information. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. To the extent this Request seeks documents and information related to the manufacture of Valsartan API, Mylan objects to this Request as overbroad, unduly burdensome, not relevant to any party’s claims or defenses, and not proportional to the needs of the Actions, in that this Request is not limited to devices, machines, or technologies used in the manufacture or testing of the specific step in the Valsartan API manufacturing process that allegedly generated NDEA. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, Mylan objects to this Request as overbroad, unduly burdensome, not relevant to any party’s claims or

defenses, and not proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDEA in Valsartan. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA and DMF files produced during core discovery.

REQUEST NO. 24: *Produce all documents relating to all patents filed by you or employees and/or agents associated with you to any foreign regulatory body regarding any manufacturing processes associated with the creation or manufacturing of valsartan, including all supporting documentation and/or correspondence associated with the filing of those patents.*

RESPONSE TO REQUEST NO. 24: Mylan incorporates the objections to Request No. 23. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to patents held by Mylan but purports to seek documents and information related to “all” patents “filed by” Mylan’s employees and/or agents, and “all” supporting documentation and correspondence related to filing, whether or not the patent was ultimately approved. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control or otherwise would require an unreasonable search of Mylan’s documents. Mylan also objects to the extent this Request is not limited to patents filed in the United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA and DMF files produced during core discovery.

REQUEST NO. 25: *Produce documents which evidence the name, address, and role of any third party which supplied you with valsartan or any ingredient, material, or component used in the manufacture of valsartan, and any evaluation or testing thereof.*

RESPONSE TO REQUEST NO. 25: Mylan objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. To the extent this Request seeks documents and information related to the manufacture of Valsartan API, Mylan objects to this Request as overbroad, unduly burdensome, not relevant to any party’s claims or defenses, and not proportional to the needs of the Actions, in that this Request is not limited to the supply and testing of ingredients, materials, or components

used in the specific step in the Valsartan API manufacturing process that allegedly generated NDEA. Mylan further objects to the extent this Request is not limited to “evaluation or testing” relating to the potential detection of NDEA. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, Mylan objects to this Request as overbroad, unduly burdensome, not relevant to any party’s claims or defenses, and not proportional to the needs of the Actions, in that this Request seeks information unrelated to the manufacture of Valsartan API, which is the process by which Plaintiffs allege the presence of NDEA arose. Mylan further objects to this Request on the grounds that the term “evaluation” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity and unreasonable in that it does not specify what type of evaluation, other than testing, is the subject of this Request. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the DMF, ANDA files, and FDA correspondence produced during core discovery. To the extent Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 26: *Produce all certificates of analysis or similar documents concerning valsartan, or documents and communications concerning the same.*

RESPONSE TO REQUEST NO. 26: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” certificates of analysis and “all . . . documents or communications concerning the same.” Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects on the basis that “similar documents” is vague and ambiguous. To the extent this Request seeks certificates of analysis related to the ingredients used to manufacture Valsartan API, Mylan objects to this Request as overbroad, unduly burdensome, not relevant to any party’s claims or defenses, and not proportional to the needs of the Actions, in that this Request is not limited to certificates of analysis for the ingredients, materials, or components used in the specific step in the Valsartan API manufacturing process that allegedly generated NDEA. To the extent this Request seeks

certificates of analysis related to the ingredients used to manufacture Valsartan finished dose, Mylan objects to this Request as overbroad, unduly burdensome, not relevant to any party's claims or defenses, and not proportional to the needs of the Actions, in that this Request is not limited to certificates of analysis for the Valsartan API used in the Valsartan finished dose. Notwithstanding the above, and subject to the objections asserted herein, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 27: *Produce complete documentation setting forth (1) each lot, batch, or other production quantity of valsartan manufactured, purchased, or sold by defendant (including discarded or recalled lots or batches), (2) the dates of manufacture/production for each, (3) the solvent(s) (including residual or reused solvents) utilized in the manufacture of each, and (4) any information you had or have with regard to potential risks of the use of any solvent utilized including residual or reused solvents.*

RESPONSE TO REQUEST NO. 27: Mylan objects to this Request as overbroad, unduly burdensome, not relevant to any party's claims or defenses, and not proportional to the needs of the Actions, in that: (1) it is not limited to lots and batches of Valsartan, whether API or finished dose, distributed in the United States market, and (2) it seeks information about lots and batches that were not subject to any recall. Mylan further objects to this request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable, and not proportional to the needs of the Actions, in that it requests production of "complete documentation." Mylan further objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, Mylan objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDEA in Valsartan. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced during core discovery. To the extent Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow

and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 28: *Produce all documents relating to all scientific journal articles submitted to any academic or scientific publication written or drafted in whole, or in part, by your employees or scientists who received funding or other forms of compensation from you, regarding the manufacturing of valsartan, including any final version, any drafts, edits, peer reviewed feedback, as well as all communications regarding any possible submission, acceptance or rejection of those journal articles.*

RESPONSE TO REQUEST NO. 28: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks documents and information related to all aspects of the manufacturing process, and requests production of “all” documents and “all” scientific journal articles, including “any” drafts, edits, feedback, and communications regarding “possible” submissions. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control or otherwise would require an unreasonable search of Mylan’s documents. To the extent this Request seeks documents and information related to the manufacture of Valsartan API, Mylan objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the specific step in the Valsartan API manufacturing process that allegedly generated NDEA. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, Mylan objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDEA in Valsartan. Mylan further objects to the extent Plaintiffs demand the production of documents in the public domain. Notwithstanding the above, and subject to the objections asserted herein, Mylan states that it is not presently aware of any documents responsive to this Request.

REQUEST NO. 29: *All documents and communications between you and any third party, outside consultant, university, or individual scientist regarding the manufacturing process associated with the creation of valsartan, including but not limited to the tetrazole ring formation process. These documents should include requests to study the manufacturing process used to create valsartan, exchange of data regarding the manufacturing process used*

to create valsartan, requests to draft academic journal articles regarding the manufacturing process used to create valsartan, and all documents sufficient to show the payments made and/or contracts between you and those third parties.

RESPONSE TO REQUEST NO. 29: Mylan objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek “documents sufficient to show” payments and contracts and therefore does not identify specific documents with reasonable particularity. To the extent this Request seeks documents and information related to the manufacture of Valsartan API, Mylan objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the specific step in the Valsartan API manufacturing process that allegedly generated NDEA. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, Mylan objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDEA in Valsartan. Notwithstanding the above, and subject to the objections asserted herein, Mylan states that it is not presently aware of any documents responsive to this Request.

IX. BIOEQUIVALENCE

REQUEST NO. 30: *All documents regarding the bioequivalence of any valsartan sold or manufactured (in whole or in part) by you to the Reference Listed Drug (“RLD”), including but not limited to, testing, correspondence with the FDA, and certifications of bioequivalence.*

RESPONSE TO REQUEST NO. 30: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents concerning “any valsartan” regardless of whether they have any bearing on the issues in the Actions. Mylan further objects to this Request as it seeks documents that are neither

relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks information concerning products other than those approved by the FDA and marketed in the United States. The Request is also objectionable on the basis that it is unlimited in time and geography. Mylan further objects to this Request as it seeks documents that are not relevant to any party's claims or defenses in that it bears no relation to the step in the Valsartan API manufacturing process that allegedly generated NDEA. As alleged in the operative Master Complaints, the purported nitrosamine impurity occurred during the API manufacturing process. (*See, e.g.*, Personal Injury Master Complaint ¶ 167; Economic Loss Master Complaint ¶ 327; Medical Monitoring Master Complaint ¶ 289.) Issues of bioequivalence relate to finished-dosage forms. Without waiving the foregoing objections, Mylan states that documents relating to bioequivalence studies, correspondence with FDA concerning bioequivalence, and certifications of bioequivalence are contained within the ANDA files and other materials previously produced during core discovery. Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan incorporates, by reference, its prior productions and related indices.

REQUEST NO. 31: *All documents and communications regarding the equivalence of any valsartan sold or manufactured (in whole or in part) by you to their RLD, including all marketing materials regarding the equivalence of your products with the RLD.*

RESPONSE TO REQUEST NO. 31: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents concerning "any valsartan" regardless of whether they have any bearing on the issues in the Actions. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks information concerning products other than those approved by the FDA and marketed in the United States. Mylan further objects to this Request as it seeks documents that are not relevant to any party's claims or defenses in that it bears no relation to the step in the Valsartan API manufacturing process that allegedly generated NDEA. The Request is also objectionable on the basis that it is unlimited in time and geography. Mylan further objects to this Request as it seeks documents that are not relevant to any party's claims or defenses. As alleged in the operative Master Complaints, the purported nitrosamine impurity occurred during the API manufacturing process. (*See, e.g.*, Personal Injury Master Complaint ¶ 167; Economic Loss Master Complaint ¶

327; Medical Monitoring Master Complaint ¶ 289.) Issues of bioequivalence relate to finished-dosage forms. Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Finally, to the extent this Request demands production of “marketing materials,” it should be noted that:

Generic products are typically not marketed to physicians or patients Generics compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete. In addition, because the generic firm promoting the product would have no way to ensure that its generic product, rather than an AB-rated generic made by one of its competitors, would be substituted for the brand by pharmacists, a substantial investment in marketing a generic product to physicians would not make sense as a practical matter.

New York v. Actavis, PLC, No. 1:14-cv-7473, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014) (citations and internal modifications omitted), *aff’d sub nom. New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015). By way of further response, and without waiving the foregoing objections, Mylan states as follows: Documents relating to bioequivalence studies, correspondence with FDA concerning bioequivalence, and certifications of bioequivalence are contained within the ANDA files and other materials previously produced during core discovery. Mylan incorporates, by reference, its prior productions and related indices. To the extent Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 32: *All documents and communications regarding the identification by any person or entity of any valsartan manufactured, utilized, or sold by or to you as not being bioequivalent to the RLD.*

RESPONSE TO REQUEST NO. 32: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents concerning “any valsartan” regardless of whether they have any bearing on the issues in the Actions. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks information concerning products other than those approved by the FDA and marketed in the United States. Mylan further objects to this Request as it seeks documents that are not relevant to any party’s claims or defenses in that it bears no relation to the step in the Valsartan API manufacturing process that allegedly generated NDEA. The Request is also objectionable on the

basis that it is unlimited in time and geography. Mylan further objects to this Request as it seeks documents that are not relevant to any party's claims or defenses. As alleged in the operative Master Complaints, the purported nitrosamine impurity occurred during the API manufacturing process. (*See, e.g.*, Personal Injury Master Complaint ¶ 167; Economic Loss Master Complaint ¶ 327; Medical Monitoring Master Complaint ¶ 289.) Issues of bioequivalence relate to finished-dosage forms. Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) By way of further answer, and without waiving the foregoing objections, Mylan states as follows: As stated in Response to Request No. 31, above, documents relating to bioequivalence studies, correspondence with FDA concerning bioequivalence, and certifications of bioequivalence are contained within the ANDA files and other materials previously produced during core discovery. Mylan incorporates, by reference, its prior productions and related indices. By way of further response, Mylan states that it is not in possession of any documents responsive to this Request.

REQUEST NO. 33: *All documents and communications relevant to valsartan entries in the FDA's "Orange Book."*

RESPONSE TO REQUEST NO. 33: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents concerning "any valsartan" regardless of whether they have any bearing on the issues in the Actions. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating Mylan's marketing of VCMs in United States. Mylan further objects to this Request as it seeks documents that are not relevant to any party's claims or defenses in that it bears no relation to the step in the Valsartan API manufacturing process that allegedly generated NDEA. Issues of bioequivalence relate to finished-dosage forms. Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents concerning any "valsartan" product regardless of whether they have any bearing on the issues in the Actions. The Request is also objectionable on the basis that it is unlimited in time and geography. Mylan further objects to this Request as it seeks documents that are not relevant to any party's claims or defenses. As alleged in the operative Master Complaints, the purported nitrosamine impurity occurred during

the API manufacturing process. (*See, e.g.*, Personal Injury Master Complaint ¶ 167; Economic Loss Master Complaint ¶ 327; Medical Monitoring Master Complaint ¶ 289.) Issues of bioequivalence relate to finished-dosage forms. Mylan objects to this Request on the basis that it is vague and ambiguous as phrased. By way of background, the *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by FDA. The main criterion for the inclusion of any product in the Orange Book is that the product is the subject of an application with an approval that has not been withdrawn for safety or efficacy reasons. Mylan has previously provided a list of all approved ANDAs concerning Valsartan medications and states that FDA has not withdrawn approval of any of those ANDAs for safety or efficacy reasons. Moreover, Mylan produced during core discovery its communications with FDA regarding the alleged impurity and the related recalls. It is therefore unclear what information Plaintiffs seek through this Request. By way of further answer, and without waiving the foregoing objections, Mylan states as follows: Documents relating to bioequivalence studies, correspondence with FDA concerning bioequivalence, and certifications of bioequivalence are contained within the ANDA files and other materials previously produced during core discovery. Mylan incorporates, by reference, its prior productions and related indices.

REQUEST NO. 34: *All documents and communications regarding any patent litigation between you and either the Brand Manufacturer of the RLD regarding valsartan, or other generic companies which had filed an ANDA application for a valsartan product including all filings, briefings, exhibits, citizen petitions, and/or correspondence with the FDA or another regulatory agency.*

RESPONSE TO REQUEST NO. 34: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents concerning “any patent litigation” regardless of whether they have any bearing on the issues in the Actions. The Request is also objectionable on the basis that it is unlimited in time and geography. Mylan further objects to this Request as it seeks documents that are not relevant to any party’s claims or defenses to the extent it seeks. Simply put, the materials pertaining to the occurrence of patent litigation relating to intellectual property issues and market entry of finished-dosage forms have no bearing on whether, as Plaintiffs allege, an impurity may have arisen during the manufacture of Valsartan API. As alleged in the operative Master Complaints, the purported nitrosamine impurity occurred during the API manufacturing process. (*See, e.g.*,

Personal Injury Master Complaint ¶ 167; Economic Loss Master Complaint ¶ 327; Medical Monitoring Master Complaint ¶ 289.) In contrast, issues of patent litigation relate to the approval and marketing of finished-dosage forms. Mylan also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. By way of further response, Mylan states that federal courts enjoy exclusive jurisdiction over patent litigation, *see* 28 USC § 1338(a), and therefore all non-privileged filings and briefings are publicly available through PACER. Likewise, citizen petitions are publicly available at www.regulations.gov. Demands for production of publicly available information equally accessible to plaintiffs are beyond the scope of permissible discovery.

X. TESTING

REQUEST NO. 35: *Produce all documents setting forth the planning, occurrence, or results of any testing (including chromatography) of valsartan that had the potential to directly or indirectly identify impurities or contamination.*

RESPONSE TO REQUEST NO. 35: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the NDEA impurities at issue in the Actions and requests the production of “all” documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the gas chromatography/mass spectrometry testing that is used to identify impurities like NDEA in valsartan. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request on the grounds that the term “planning” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party’s claim or defense nor proportional to the needs of each case, in that it purports to seek documents pertaining to logistical arrangements. Mylan further objects to this Request on the grounds that the phrase “had the potential to directly or indirectly identify” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party’s claim or defense nor proportional to the needs of each case, in that it

purports to seek documents that are not directly related to the NDEA impurities at issue in these Actions. By way of further answer, Mylan states as follows: Impurities like NDEA can only be identified through gas chromatograph/mass spectrometry testing, and methods to detect impurities at the levels associated with Mylan's recalls of Valsartan were not developed after the initial recalls of VCMs were announced in July 2018. Any other test is not designed to, intended to, or sufficiently sensitive to identify the alleged NDEA impurities at issue and are therefore not relevant to these Actions. Notwithstanding the above, and subject to the objections asserted herein, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 36: *Produce all documentation with regard to the first test that indicated contamination of valsartan that was potentially due to a nitrosamine, whether or not identified at the time.*

RESPONSE TO REQUEST NO. 36: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the NDEA impurities at issue in the Actions and requests the production of "all" documentation. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the gas chromatography/mass spectrometry testing that is used to identify impurities like NDEA in Valsartan. Mylan further objects to this Request as vague, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as "all documentation" does not identify any particular set of documents and is duplicative of other Requests, including Request No. 35. By way of further answer, Mylan states as follows: Impurities like NDEA can only be identified through gas chromatograph/mass spectrometry testing, and methods to detect impurities at the levels associated with Mylan's recalls of Valsartan were not developed after the initial recalls of VCMs were announced in July 2018. Mylan incorporates, by reference, the FDA correspondence it produced in connection with the core discovery process, which contains the information Plaintiffs seek.

REQUEST NO. 37: *Produce all documentation with regard to each notification to defendant of contamination of valsartan that was, or potentially was, due to a nitrosamine, including the full documentation of the testing and analysis that led to the identification of the actual or potential contamination. In connection with this request, separately identify the first such notification.*

RESPONSE TO REQUEST NO. 37: Mylan incorporates, by reference, its Response to Request No. 36.

REQUEST NO. 38: *Produce all documents or communications with regard to the actual or attempted detection of impurities or contaminants in valsartan or any component or ingredient thereof, including chromatographs, and intermediate testing.*

RESPONSE TO REQUEST NO. 38: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited the impurities at issue in these Actions and requests the production of “all” documents or communications. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the gas chromatography/mass spectrometry testing that is used to identify impurities like NDEA in Valsartan. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions in that it purports to seek testing of ingredients used in the manufacture of finished-dose Valsartan, while the Master Complaints allege that the impurities arise from the Valsartan API manufacturing process. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request as vague, overbroad, and unduly burdensome, lacking in particularity, and unreasonable, as “all documents and communications” does not identify any particular set of documents and is duplicative of other Requests, including Requests No. 35 and 36. By way of further answer, Defendant states as follows: As stated in Response to Request No. 35, above, tests other than gas chromatography/mass spectrometry are not relevant to these Actions. Notwithstanding the above, and subject to the objections asserted herein, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 39: *Produce all documents with regard to evaluation by an employee of defendant or a third party, of the health risks of valsartan contamination.*

RESPONSE TO REQUEST NO. 39: Mylan objects to those parts of this Request as overbroad, unduly burdensome, and not proportional to needs of the Actions, in that they are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as it is not limited to the impurities at issue in these Actions and requests the production of “all” documents. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request to the extent that the term “health risks” is not limited to the health risks associated with Valsartan and Valsartan API as alleged in the Master Complaints, is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party’s claim or defense nor proportional to the needs of each case. Notwithstanding the above, and subject to the objections asserted herein, Mylan states that it has already produced as part of core discovery the Medical Risk Assessment it conducted in connection with the recall of Valsartan. To the extent Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 40: *Produce all documents relating, referring to or embodying studies on the safety, ingredients, impurities, and contamination, of valsartan conducted by any third parties, including, but not limited to, those conducted by Contract Research Organizations (CRO), educational institutions, publicly or independently funded groups, competitors, trade groups or associations, regulatory entities, irrespective of whether such studies were conducted at the direction of Defendant.*

RESPONSE TO REQUEST NO. 40: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to studies relating to the impurities at issue in this case and requests the production of “all” documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the gas chromatography/mass spectrometry testing that is used to identify impurities like NDEA in valsartan. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s

possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to the extent the request seeks documents available in the public realm equally available to Plaintiffs. By way of further response, Defendant states as follows: As stated in response to Request No. 35, above, tests other than gas chromatography/mass spectrometry are not relevant to these Actions. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the DMF, ANDA files, and FDA correspondence produced over the course of the core discovery process. If Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 41: *Produce all documents concerning any receipt, discussion, studies, analysis or review of clinical experience reports for valsartan, including, but not limited to, formally submitted adverse reaction reports, communications (whether written or oral), case reports, published clinical experience reports, or any other such report made known to Defendant concerning valsartan including, but not limited to: 1) the relationship between the use of contaminated valsartan and potential or confirmed injuries; b) investigator reported events identified by patient number and relevant records; and c) any employee or consultant who reviewed and/or adjudicated such events for causation.*

RESPONSE TO REQUEST NO. 41: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks case reports, clinical experience reports, and any other reports that are not related to the impurities, injuries, or products at issue in the Actions. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request on the grounds that the term "investigator reported events" is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable. Mylan further objects to the extent the Request seeks public documents equally available to Plaintiffs. Mylan also objects on the basis that the information sought by Plaintiffs is not relevant to or admissible on any issue relevant to this litigation.

Notwithstanding the above, and subject to the objections asserted herein, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 42: *As to any clinical or animal study regarding valsartan, whether or not sponsored by, financed by, undertaken by, or suggested by Defendant, provide all documents concerning said study, including, but not limited to, analysis and conclusions, engagement letters, contracts, agreements with investigators, agreements with study locations, protocols, status reports, raw data, summary of findings, internal memoranda, drafts of reports, final reports, manuscripts, submissions to publishers, submissions to any regulatory authority.*

RESPONSE TO REQUEST NO. 42: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to studies related to the NDMA and NDEA impurities at issue in the Actions and requests the production of “all” documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions because, to the extent clinical or animal studies may exist, they bear no relation to NDMA and NDEA impurities. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to the extent the request seeks public documents equally available to Plaintiffs. Further, Plaintiffs’ claims are based on recalls pursuant to FDA regulations. Therefore, production of documents regarding “any regulatory authority” is overbroad, unduly burdensome, and not proportional to the needs of the Actions. By way of further response, Mylan states that it has not conducted “animal” studies with respect to VCMs and any “clinical” study would be contained in the ANDA files which have already been produced.

REQUEST NO. 43: *Produce all documents relating, referring to or embodying any epidemiology studies or analyses known to defendant regarding valsartan, including but not limited to, any provided to or received from any regulatory authority, SAS data sets, combined analysis or pooled analysis whether or not published in medical literature or submitted to any regulatory authority, study hypotheses, test protocols, data compilations, summaries of results, drafts of reports, final reports, published or unpublished articles or studies, presentations and poster sessions, compensation, engagement of investigators, investigators’ brochures, and internal memoranda.*

RESPONSE TO REQUEST NO. 43: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to testing conducted at Mylan's direction and requests the production of "all" documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it is not limited to studies or analyses pertaining to Valsartan API containing NDMA or NDEA impurities. Mylan further objects to this Request in that it seeks documents or information that are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Further, Plaintiffs' claims are based on recalls pursuant to FDA regulations. Therefore, production of documents regarding "any regulatory authority" is overbroad, unduly burdensome, and not proportional to the needs of the Actions. Mylan also objects to the extent Plaintiffs demand production of documents in the public domain or relating to injuries other than those allegedly experienced by Plaintiffs. Notwithstanding the above, and subject to the objections asserted herein, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 44: *Produce documents sufficient to show (a) all testing, prior to any recall, of valsartan you manufactured or sourced, (b) all testing, after any recall, of valsartan you manufactured or sourced, (c) the results of the foregoing testing; (d) any testing that was considered but not performed before or after any recall, including the reason(s) why such testing was not performed, and (e) to the extent any lot, batch, or other production quantity was not tested for impurities or contamination, complete documentation with regard to the reason(s) why no such testing was performed.*

RESPONSE TO REQUEST NO. 44: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to testing conducted at Mylan's direction and requests the production of "all" documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the gas chromatography/mass spectrometry testing that is used to identify impurities like NDEA. Mylan further objects to this Request as it seeks documents that are neither

relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it is not limited to studies or analyses pertaining to Valsartan API containing NDMA or NDEA impurities. Mylan further objects to this Request in that it seeks documents or information that are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan also objects to the extent Plaintiffs demand production of documents in the public domain or relating to injuries other than those allegedly experienced by Plaintiffs. Mylan also objects on the basis that the Request does not describe with reasonable particularity the documents sought insofar as Plaintiffs demand production of materials relating to "testing that was . . . not performed" and the "reason(s) why such testing was not performed." By way of further answer, Mylan states as follows: Impurities like NDEA can only be identified through gas chromatograph/mass spectrometry testing, and methods to detect impurities at the levels associated with Mylan's recalls of Valsartan were not developed after the initial recalls of VCMs were announced in July 2018. Any other test is not designed to, intended to, or sufficiently sensitive to identify the alleged NDEA impurities at issue and are therefore not relevant to these Actions. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the DMF, ANDA files, and FDA correspondence produced over the course of the core discovery process, which address testing performed in connection with the manufacture of Valsartan API and the recalls of VCMs. If Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

XI. NITROSAMINES AND CONTAMINATION

REQUEST NO. 45: *Produce complete documentation identifying each lot, batch, or other production quantity of valsartan, and whether and how or why: (a) each was confirmed to be contaminated and the quantification of the contamination; (b) each was assumed to have been contaminated and the quantification of the contamination; (c) each was confirmed not to be contaminated; (d) each was assumed not to be contaminated, and (e) each was not confirmed or assumed to be contaminated.*

RESPONSE TO REQUEST NO. 45: Mylan objects to this Request to the extent it is duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects as overbroad, unduly burdensome, and not proportional to the needs of the Actions,

in that it is not limited to Valsartan sold or distributed into the United States market and requests the production of “complete” documents concerning “each” lot or batch of valsartan, regardless of whether they have any bearing on the issues in the Actions. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. The Request is also objectionable on the basis that it is unlimited in time and geography. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Rule 34. Finally, Mylan further objects to this Request as is improper insofar as it is vague and ambiguous, lacking in particularity, and unreasonable in that it demands production of documents purporting to identify “whether and how or why” medication was confirmed or “assumed” to be “contaminated.” Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced during the core discovery process. To the extent Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 46: *Produce all documents with regard to any nitrosamine compound, including but not limited to NDMA, NDEA, NMBA, and any other nitrosamine or carcinogenic contaminant that has been directly or indirectly tested for and/or identified in valsartan or any other API or finished drug manufactured, formulated, distributed, or sold by the answering defendant.*

RESPONSE TO REQUEST NO. 46: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan sold or distributed into the United States market and requests the production of “all” documents concerning “any” nitrosamine, regardless of whether they have any bearing on the issues in the Actions and regardless of whether the information exists in the public realm. Mylan further objects to this Request as it seeks documents

that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of each case, in that it purports to seek information about unspecified "other" impurities. Moreover, the only impurities presently at issue in this MDL are NDMA and NDEA. (*See* Dkt. 1, Transf. Or., at 2.) Plaintiffs' request for production of documents relating to unspecified "other" impurities in "any other" API or finished drug is improper and irrelevant as the only API and finished drugs presently at issue in this MDL are valsartan medications. (*See* Dkt. 1, Transf. Ord., at 2.). The Request is also objectionable on the basis that it is unlimited in time and geography. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Rule 34. By way of further answer, Mylan states as follows: Taken literally, this Request would obligate Mylan to produce, for example, publicly available literature and FDA statements—all of which is quite clearly beyond the scope of permissible discovery. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the DMF, ANDA files, and FDA correspondence produced over the course of the core discovery process. If Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 47: *Produce all documents evidencing any testing or research conducted by you to determine the existence or amount of contamination in any valsartan API or finished drug formulation. . [sic]*

RESPONSE TO REQUEST NO. 47: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan sold or distributed into the United States market and requests the production of "all" documents concerning "any testing or research," regardless of

whether they have any bearing on the issues in the Actions and regardless of whether the information exists in the public realm. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the NDMA and NDEA impurities at issue in this case. To the extent Plaintiffs request production of documents relating to unspecified other impurities, it is improper and irrelevant. The Request is also objectionable on the basis that it is unlimited in time and geography. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Rule 34. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the DMF, ANDA files, and FDA correspondence produced over the course of the core discovery process. If Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 48: *Produce all documents and communications with regard to the health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance.*

RESPONSE TO REQUEST NO. 48: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents concerning "any" carcinogenic substance and "health risks," regardless of whether they have any bearing on the issues in the Actions and regardless of whether the information exists in the public realm. Indeed, taken literally, this Request would obligate Mylan to produce publicly available literature and FDA statements—all of which is quite clearly beyond the scope of permissible discovery. Moreover, the only impurities presently at issue in this MDL are NDMA and NDEA. (*See* Dkt. 1, Transf. Or., at 2.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the NDMA and NDEA impurities at issue in

this case. Mylan further objects to this Request to the extent the term “health risks” is not limited to the health risks associated with Valsartan and Valsartan API as alleged in the Master Complaints and, therefore, the Request is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party’s claim or defense nor proportional to the needs of each case. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. The Request is also objectionable on the basis that it is unlimited in time and geography. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Rule 34. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the DMF, ANDA files, and FDA correspondence produced over the course of the core discovery process. If Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 49: *Produce all studies, data, or other scientific or medical information reviewed or considered by any employee with regard to the health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance.*

RESPONSE TO REQUEST NO. 49: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the NDMA and NDEA impurities at issue in this case and requests the production of “all” information reviewed by “any” employee concerning “any” carcinogenic substance and “health risks,” regardless of whether they have any bearing on the issues in the Actions and regardless of whether the information exists in the public realm. The Federal Rules of Civil Procedure do not obligate a party to produce publicly available documents, such as medical literature and FDA statements. Moreover, the only impurities presently at issue in this MDL are NDMA and NDEA. (*See* Dkt. 1, Transf. Or., at 2.) Plaintiffs’ request for production

of documents relating to unspecified “other” impurities is improper and irrelevant. Mylan further objects to this Request on the grounds that the term “health risks” is not limited to the health risks associated with Valsartan and Valsartan API as alleged in the Master Complaints, is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party’s claim or defense nor proportional to the needs of each case. The Request is also objectionable on the basis that it is unlimited in time and geography. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process. If Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 50: *Produce all formal or informal reports or complaints by or to any person or entity with regard to valsartan contamination.*

RESPONSE TO REQUEST NO. 50: Mylan objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the NDMA and NDEA impurities at issue in this case and requests the production of “all” reports to “any person or entity,” regardless of whether they have any bearing on the issues in the Actions and regardless of whether the information exists in the public realm. The Federal Rules of Civil Procedure do not obligate a party to produce publicly available documents, such as medical literature, legal filings, and FDA statements. Moreover, the only impurities presently at issue in this MDL are NDMA and NDEA. (*See* Dkt. 1, Transf. Or., at 2.) To the extent this Request seeks information regarding other impurities, it is improper and irrelevant. The Request is also objectionable on the basis that it is unlimited in time and geography. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents.

Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process. And, with regard to Plaintiffs’ request for production of “complaints,” Mylan incorporates by reference its Response to Request No. 17. If Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 51: *Produce every document relating, referring to or embodying any opinion by a physician, or a scientist, or a medical or scientific expert, given after the first notification of potential nitrosamine contamination of valsartan, regarding the safety or efficacy of valsartan including, but not limited to internal documents, reports prepared in legal proceedings, opinions expressed in depositions or trial, reports submitted to scientific journals, opinions expressed at medical conferences and opinions provided as testimony, reports or statements to the FDA or any regulatory authority, or any advisory committee thereof.*

RESPONSE TO REQUEST NO. 51: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the NDMA or NDEA impurities at issue in this case and requests the production of “every” document relating to “any opinion” regarding the safety of valsartan, regardless of whether they have any bearing on the issues in the Actions and regardless of whether the information exists in the public realm. The Federal Rules of Civil Procedure do not obligate a party to produce publicly available documents, such as medical literature and FDA statements. Moreover, the only impurities presently at issue in this MDL are NDMA and NDEA. (See Dkt. 1, Transf. Or., at 2.) To the extent this Request seeks information regarding other impurities, it is improper and irrelevant. The Request is also objectionable on the basis that it is unlimited in geography. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Mylan further objects to the extent Plaintiffs purport to demand the production or identification of materials selected by counsel on the basis of the attorney–client

privilege and the work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process, which includes the Medical Risk Assessment performed by Mylan. If Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

XII. REGULATORY CORRESPONDENCE AND DOCUMENTS

REQUEST NO. 52: *Produce all regulatory documentation and communications with regard to contamination or recalls of valsartan.*

RESPONSE TO REQUEST NO. 52: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the impurities allegedly at issue in this litigation or the specific step in the Valsartan API manufacturing process that allegedly generated NDEA. Further, Plaintiffs’ claims are based on recalls pursuant to FDA regulations. Therefore, documents regarding foreign regulations and communications with foreign regulators are not relevant to these Actions. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the DMF, ANDA files, and FDA correspondence produced over the course of the core discovery process. If Plaintiffs seek additional information, Mylan is willing to engage in a meet-and-confer with Plaintiffs to narrow and more properly define the scope of this Request, because, as written, it is beyond the scope of permissible discovery.

REQUEST NO. 53: *Produce all regulatory documentation and communications with regard to any aspect of the manufacturing process for valsartan.*

RESPONSE TO REQUEST NO. 53: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan

further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the specific step in the Valsartan API manufacturing process that allegedly generated NDEA. To the extent this Request seeks documents and information related to the manufacture of Valsartan API, Mylan objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the specific step in the Valsartan API manufacturing process that allegedly generated NDEA. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, Mylan objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDEA in Valsartan. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as “all documentation or communications with regard to any aspect of the manufacturing process” does not identify any particular set of documents and is duplicative of many other Requests, including Requests No. 20–21 and 23–29. Further, Plaintiffs’ claims are based on recalls pursuant to FDA regulations. Therefore, documents regarding foreign regulations and communications with foreign regulators are not relevant to these actions. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, DMF, and FDA correspondence produced during core discovery. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 54: *Produce transcripts, notes, memoranda, or other documentation of any hearings or other proceedings or meetings which took place at or with any regulatory agency relating to the actual and/or potential contamination or recall of valsartan.*

RESPONSE TO REQUEST NO. 54: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan

further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses or proportional to the needs of the Actions in that it is not limited to proceedings that took place with domestic regulatory agencies. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent any transcripts, notes, memoranda, or other documentation of any hearing or any other proceeding or meeting with any regulatory agency bear no relation to alleged impurities at issue. Further, Plaintiffs' claims are based on recalls pursuant to FDA regulations. Therefore, production of documents regarding "any regulatory agency" is overbroad, unduly burdensome, and not proportional to the needs of the Actions. Documents regarding foreign regulations and communications with foreign regulators are not relevant to these Actions. Mylan also objects to the extent this Request seeks information in the public domain or otherwise equally accessible to Plaintiffs. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced during core discovery. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 55: *Produce all documents with regard to any FDA Advisory Panel meetings regarding valsartan contamination, including but not limited to:*

- a. All documents relating or referring to any communications between Defendant (or any agent or consultant of Defendant), and the FDA or any Advisory Panel Member;*
- b. All documents relating to or referring to any financial contributions or other items of value provided by Defendant to Panel Members or their institutions/organizations; and*
- c. All documents relating, referring to or embodying minutes of meetings, agendas, dossiers, submissions, test summaries, internal memoranda regarding strategies and issues, Questions and Answers, scheduling, or any other documents concerning the Advisory Panel, submissions thereto, or the topic(s) discussed.*

RESPONSE TO REQUEST NO. 55: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents. Mylan objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the specific step

in the Valsartan API manufacturing process that allegedly generated NDEA. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, and duplicative of many other Requests, including Request No. 52. Mylan also objects on the basis that this Request seeks documents in the public realm, equally accessible to Plaintiffs. Notwithstanding the above, and subject to the objections asserted herein, Mylan states that it is not aware of any involvement of an FDA Advisory Panel with respect to the potential presence of NDMA or NDEA in Valsartan. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 56: *Produce all Establishment Inspection Reports and related documentation (including photographs or video) concerning your facilities or the facilities of any other defendant relating to valsartan or any equipment or systems used in the manufacture, fabrication, packaging, distribution, or sale of valsartan.*

RESPONSE TO REQUEST NO. 56: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents. Mylan also objects to the extent this Request seeks materials concerning inspections conducted by regulatory authorities other than FDA. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the machines, materials, and substances used during the specific step in the Valsartan API manufacturing process that allegedly generated NDMA or NDEA. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced during core discovery, which included Establishment Inspection Reports and related documentation for the facilities where MLL has manufactured Valsartan API.

REQUEST NO. 57: *Produce all documents relating, referring to or embodying all inspection reports (including 483s, detention reports, and warning letters) or consent decrees which pertain in any way to valsartan contamination or any facility in which contaminated valsartan was manufactured, marketed, distributed or otherwise stored.*

RESPONSE TO REQUEST NO. 57: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan

objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents and is not limited to documents relating to the manufacture of Valsartan API. Mylan also objects to the extent this Request seeks materials concerning inspections conducted by regulatory authorities other than FDA. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the machines, materials, and substances used during the specific step in the Valsartan API manufacturing process that allegedly generated NDMA or NDEA. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced during core discovery, which included Establishment Inspection Reports and related documentation for the facilities where MLL has manufactured Valsartan API.

REQUEST NO. 58: *Produce complete documentation regarding any CAPAs (Corrective and Preventative Actions) relating to valsartan, including documentation showing what caused the CAPA to be opened and/or closed.*

RESPONSE TO REQUEST NO. 58: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents. Mylan objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012 and unrelated to the manufacture of Valsartan API. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the specific step in the Valsartan API manufacturing process that allegedly generated NDMA or NDEA. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Mylan also objects to the extent Plaintiffs seek information which would not be admissible pursuant to Rule 407 of the Federal Rules of Evidence. Notwithstanding the above, and subject to the objections asserted herein, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 59: *Produce all documentation, and related communications, of any complaints or third party communications to or from any regulatory agency with regard to actual or potential valsartan contamination.*

RESPONSE TO REQUEST NO. 59: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects on the basis that this Request is vague and ambiguous as phrased. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to domestic regulatory agencies and it requests the production of “all” documents. Mylan objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the specific step in the Valsartan API manufacturing process that allegedly generated NDMA or NDEA. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, and duplicative of many other Requests, including Request No. 52. Further, Plaintiffs’ claims are based on recalls pursuant to FDA regulations. Therefore, production of documents regarding foreign regulatory agencies is overbroad, unduly burdensome, and not proportional to the needs of the Actions. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced as part of the core discovery process. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 60: *Produce all documentation, including source files, for any MAUDE or other adverse event reports submitted to any regulatory agency with regard to valsartan contamination, and any related communications.*

RESPONSE TO REQUEST NO. 60: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of “all” documents. The Request is also objectionable on the basis that it is unlimited in time and geography. Further, Plaintiffs’ claims are based on recalls pursuant to FDA regulations. Therefore, production of documents regarding

foreign regulatory agencies is overbroad, unduly burdensome, and not proportional to the needs of the Actions. Mylan objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the specific step in the Valsartan API manufacturing process that allegedly generated NDMA or NDEA or the injuries alleged in the Master Complaints. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, and duplicative of many other Requests, including Request No. 52. Finally, Mylan states that the pharmacovigilance materials sought by way of this Request are irrelevant and inadmissible for any purpose. Notwithstanding the above, and subject to the objections asserted herein, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 61: *Produce complete files for all formal or informal adverse event reports and/or MedWatch reports concerning valsartan, including: a) causation analyses, b) summaries (including, but not limited to, computerized data), analysis or interpretations of any such adverse event report(s) (including any post-marketing submissions); and c) documents which discuss or refer to any adverse event report, or any summary, analysis or interpretation thereof.*

RESPONSE TO REQUEST NO. 61: Mylan incorporates, by reference, its Response to Request No. 60.

REQUEST NO. 62: *Produce all databases maintained by you concerning both domestic and international formal and informal adverse event reports and/or MedWatch reports, including the underlying medical information and raw data maintained by you.*

RESPONSE TO REQUEST NO. 62: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents and with no relation to the VCMs, impurities, or injures allegedly at issue in this litigation. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the specific step in the Valsartan API manufacturing

process that allegedly generated NDMA or NDEA. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, and duplicative of many other Requests, including Request Nos. 52, 60, and 61. Further, Plaintiffs' claims are not based on recalls pursuant to FDA regulations. Therefore, production of documents regarding foreign regulatory agencies is overbroad, unduly burdensome, and not proportional to the needs of the Actions. Finally, Mylan states that the pharmacovigilance materials sought by way of this Request are irrelevant and inadmissible for any purpose.

REQUEST NO. 63: *Produce all filings with the Securities and Exchange Commission (SEC), addressing any issues related to the sale of contaminated valsartan, including Forms 10-K, 10-Q, 8-K, and proxy statement (Schedule 14A), whether such filings are tentative, final, definitive, or supplemental.*

RESPONSE TO REQUEST NO. 63: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" filings. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to NDEA or the specific step in the Valsartan API manufacturing process that allegedly generated NDMA or NDEA. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Mylan also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient.

REQUEST NO. 64: *Produce complete documentation of any communications with any state regulatory or health authorities regarding valsartan ingredients, purity, contamination, or pricing.*

RESPONSE TO REQUEST NO. 64: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88). Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "any communications." Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the NDMA or NDEA impurities

at issue in this case or to the specific step in the Valsartan API manufacturing process that allegedly generated NDMA or NDEA. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, and duplicative of many other Requests, including Request No. 52. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it seeks information predating its sale of VCMs in the United States. Mylan objects to this Request in that the term "state regulatory and health authorities" is vague and ambiguous. Mylan understands this Request as seeking production of communications with regulators from the 50 states of the United States.

REQUEST NO. 65: *Produce all documents and communications concerning, with respect to valsartan, all efforts to comply with Current Good Manufacturing Practices (cGMPs), and any actions or inactions that did not meet or might not have met cGMPs.*

RESPONSE TO REQUEST NO. 65: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents relating to "any" actions. Mylan objects on the basis that it is vague and ambiguous as phrased and, therefore, does not describe with sufficient particularity the materials sought. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that it is not limited to the NDMA or NDEA impurities at issue in this case or to the specific step in the Valsartan API manufacturing process that allegedly generated NDMA or NDEA. To the extent this Request seeks documents and information related to the manufacture of Valsartan finished dose, Mylan objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDEA in Valsartan. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, DMF, and FDA correspondence produced over the course of the core discovery process. To the extent Plaintiffs demand additional information in response to this

Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

XIII. COMPLAINTS AND RECALLS

REQUEST NO. 66: *Produce all documents and communications with regard to any consideration or implementation of a recall due to contamination of valsartan.*

RESPONSE TO REQUEST NO. 66: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to documents related to recalls of VCMs in the United States market or to the communications regarding the recalls, products, and impurities at issue in the Actions. Mylan also objects to this Request as it seeks documents or information readily accessible to Plaintiffs from the Defendants' core discovery productions, and in that it requests the production of "all" documents and communications. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request on the grounds that the terms "consideration," "implementation," and "due to" are vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of each case, in that they purport to seek documents not directly related to the recalls, products, or impurities at issue in the Actions. Further, Plaintiffs' claims are based on recalls of Valsartan in the United States market pursuant to FDA regulations. Therefore, documents regarding recalls pursuant to foreign regulations are not relevant to these Actions. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage

in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 67: *Produce all draft recall notices with regard to contamination of valsartan.*

RESPONSE TO REQUEST NO. 67: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls of product in the United States market or to the recalls, products, and impurities at issue in the Actions. Mylan further objects to this Requests as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it calls for production of drafts of documents without any basis whatsoever, seeks documents or information readily accessible to Plaintiffs from the Defendants' core discovery productions, and requests the production of "all" recall notices. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process, which includes draft recall notices.

REQUEST NO. 68: *Produce all final recall notices with regard to contamination of valsartan.*

RESPONSE TO REQUEST NO. 68: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls of product in the United States market or to the NDMA and NDEA impurities at issue in the Actions, and in that it requests the production of "all" recall notices. Notwithstanding the above, and subject to the objections asserted herein, Mylan states that the notices of recall of Mylan's VCMs are publicly available and, in any event, have already been produced during core discovery.

REQUEST NO. 69: *Produce all documents and communications relating to or directly with any customer or consumer relating to the recall (or non-recall) of valsartan due to contamination.*

RESPONSE TO REQUEST NO. 69: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls of product in the United States market. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the recalls, products, and impurities at issue in the Actions, seeks documents or information publicly available to the Plaintiffs and/or readily or more accessible to Plaintiffs from Plaintiffs' own files, from documents or information in Plaintiffs' possession and/or from Defendants' core discovery productions, and requests the production of "all" documents and communications with "any" customer or consumer. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan also objects on the basis that the demand for communications relating to a "non-recall" is vague, ambiguous, and potentially overbroad. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 70: *Produce all documents and communications relating to communications directly with physicians relating to the recall (or non-recall) of valsartan due to contamination.*

RESPONSE TO REQUEST NO. 70: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls of product in the United States market. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the recalls, products, and impurities at issue in the Actions, seeks documents or information publicly available to the Plaintiffs and/or readily or more accessible to Plaintiffs from Plaintiffs' own files, from documents or information in Plaintiffs' possession and/or from Defendants' core discovery productions, and requests the production of "all" documents and

communications with unnamed physicians. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan also objects on the basis that the demand for communications relating to a "non-recall" is vague, ambiguous, and potentially overbroad. Notwithstanding the above, and subject to the objections asserted herein, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 71: *Produce all documents and communications with any person or entity from or to which you purchased or sold valsartan, with regard to valsartan contamination.*

RESPONSE TO REQUEST NO. 71: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to purchases and sales of VCMs in the United States market. Mylan further objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the recalls, products, and impurities at issue in the Actions, seeks documents or information publicly available to the Plaintiffs and/or readily or more accessible to Plaintiffs from Plaintiffs' own files, from documents or information in Plaintiffs' possession and/or from Defendants' core discovery productions, and requests the production of "all" documents and communications with "any" unnamed "person or entity." Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan also objects on the basis that the Request seeks information predating Mylan's sales of VCMs in the United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 72: *Produce all documents and communications with regard to the scope of any recall considered or implemented with regard to valsartan contamination.*

RESPONSE TO REQUEST NO. 72: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to recalls “considered or implemented” in the United States. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the recalls, products, and impurities at issue in the Actions, seeks documents or information publicly available to the Plaintiffs and/or readily or more accessible to Plaintiffs from Plaintiffs’ own files, from documents or information in Plaintiffs’ possession and/or from Defendants’ core discovery productions, and requests the production of “all” documents and communications of a given nature. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 73: *Produce all documents and communications with regard to any complaint or concern raised by any person or entity relating to the quality or purity of valsartan.*

RESPONSE TO REQUEST NO. 73: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited VCMs purchased or used in the United States market. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan also objects on the basis that “complaint or concern” and “quality” are undefined and ambiguous as phrased. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions,

in that it is not limited to the recalls, products, and impurities at issue in the Actions, seeks documents or information publicly available to the Plaintiffs and/or readily or more accessible to Plaintiffs from Plaintiffs' own files, from documents or information in Plaintiffs' possession and/or from Defendants' core discovery productions, and requests the production of "all" documents and communications with regard to "any" complaint or concern" raised by any unnamed "person or entity." Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan also objects on the basis that the Request seeks information predating Mylan's sales of VCMs in the United States. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 74: *Produce all documents and communications concerning any actual or potential import or export alerts relating to valsartan contamination.*

RESPONSE TO REQUEST NO. 74: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to regulatory actions by FDA. Mylan further objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the recalls, products, and impurities at issue in the Actions, seeks documents or information publicly available to the Plaintiffs and/or readily or more accessible to Plaintiffs from Plaintiffs' own files, from documents or information in Plaintiffs' possession and/or from Defendants' core discovery productions, and requests the production of "all" documents and communications with regard to

“any” alert. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan also objects on the basis that the Request seeks information predating Mylan’s sales of VCMs in the United States. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 75: *Produce all documents and communications concerning any refunds that you paid to purchasers of valsartan in the United States from January 1, 2010 to the present, including but not limited to retail pharmacies, direct purchasers, wholesale distributors, and TPPs.*

RESPONSE TO REQUEST NO. 75: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to refunds issued in connection with the recall of VCMs or the potential presence of NDEA. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the recalls, products, and impurities at issue in the Actions and requests the production of “all” documents and communications with regard to “any” refund to any purchaser, irrespective of whether the refund has any bearing on this litigation. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan also objects on the basis that the Request seeks information predating Mylan’s sales of VCMs in the United States. Mylan further objects to this Request to the extent that it calls

for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process, which includes information regarding the issuance of refunds in connection with Mylan’s recalls of VCMs. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 76: *Produce all documents and communications regarding recall of valsartan, provided to consumers, physicians, and TPPs, including lists sufficient to show all persons or entities who received communications notifying them of the recall, the contents of all communications contained in the letters notifying persons of the recall, documentation tracking all correspondence and communications related to the recall, all drafts of letters or other communications created to notify consumers of the recall.*

RESPONSE TO REQUEST NO. 76: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to communications concerning recalls initiated in the United States. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the recalls, products, and impurities at issue in the Actions, demands the production of documents in the public realm or otherwise equally accessible to Plaintiffs, and requests the production of “all” documents and communications to virtually any person or entity. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process, which includes information regarding the preparation (including drafts) and issuance of Mylan’s notices of recall of VCMs. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more

appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 77: *Produce all documents relating, referring to or embodying the hiring or retention by any Defendant or by any other person or entity acting on any defendant's behalf, of any public relations firm or any law firm specializing in drug regulatory practices to participate in, orchestrate, organize or otherwise direct any evaluation of recall discussions for valsartan and produce all documents regarding said engagement, including, but not limited to, questions and answer, talk papers, scripts for telephone calls, creation of special advisory or consulting board, gestures to demonstrate concern for victims, donations to causes important to victims, retention of scientific or medical researchers, advisors or experts and other such public relations strategies.*

RESPONSE TO REQUEST NO. 77: Mylan objects on the basis that this Request uses vague, ambiguous, and undefined terms and, moreover, information relating to “public relations strategies” is irrelevant to the issues presented in this litigation. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to information concerning recalls initiated in the United States. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the recalls, products, and impurities at issue in the Actions and requests the production of “all” documents and communications by “any” Defendant to “any” firm. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine.

REQUEST NO. 78: *Produce all documents with regard to, or communications with, Novartis concerning valsartan, including but not limited to, documents or communications relating to testing or evaluation of valsartan, contamination, impurities, recalls, pre-commercial negotiations, contracts (including all draft contracts), product specifications, testing specifications, complaints, responses to complaints, investigations, meeting notes, presentations, and communications with any regulatory authority.*

RESPONSE TO REQUEST NO. 78: Mylan objects on the basis that this Request uses vague, ambiguous, and undefined terms and, moreover, much of the information requested is irrelevant to the issues presented in this litigation. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking

in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the recalls, products, and impurities at issue in the Actions and requests the production of “all” documents and communications irrespective of whether the information has any bearing on the issues presented in the Actions. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Mylan also objects to the extent this Request seeks information predating Mylan’s sale of VCMs in United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files produced over the course of the core discovery process, which includes information regarding the regulatory process by which Mylan received FDA approval to market VCMs.

XIV. WARRANTIES AND STATEMENTS

REQUEST NO. 79: *Produce all versions of defendant’s labeling for valsartan, together with a chart of the approval dates and in use dates for all versions that were utilized in the sale and marketing of valsartan.*

RESPONSE TO REQUEST NO. 79: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to issues pertaining to alleged contamination of Valsartan API with NDEA and requests the production of “all” documents. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to labels on Valsartan sold or distributed into the United States market. Mylan also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. Mylan further objects to this Request as overbroad and unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to topics reasonably related to the alleged contamination of Valsartan API with NDMA

or NDEA and, instead, seeks documents relating to the labeling, sale, and marketing of Valsartan finished dose. Mylan further objects to this Request in that it seeks documents or information that are unduly burdensome to locate or obtain, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Further, Plaintiffs' claims are based on recalls pursuant to FDA regulations. Therefore, documents regarding labeling, selling, and/or marketing of Valsartan API or Valsartan finished dose product outside the U.S. market are not relevant to these Actions. Mylan also objects to the extent this Request seeks information predating Mylan's sales of VCMs in the United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence and ANDA files produced over the course of the core discovery process, which include information regarding Mylan's FDA-approved labeling for VCMs. Mylan states further that FDA-approved labeling for VCMs is publicly available.

REQUEST NO. 80: *Documents sufficient to show all (past and present) labels and packaging materials, including all associated documentation and disclosures provided to medical professionals, purchasers, including TPPs, consumers, wholesale distributors, retail pharmacies, and other direct and indirect purchasers of valsartan, for each NDC, Batch Number, and Lot Number of valsartan sold in the United States from January 1, 2010 to the present, including copies and drafts of all such materials, and documents sufficient to show the time period during which each exemplar was in use.*

RESPONSE TO REQUEST NO. 80: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to issues pertaining to alleged contamination of Valsartan API with NDEA and requests the production of "all" documents fitting within numerous categories. Mylan also objects on the basis that the Request uses vague and ambiguous terms, including the qualifier, "sufficient to show." Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to labels on Valsartan sold or distributed into the United States market. Mylan also objects to this request to the extent it seeks information that is publicly available or available from another source

that is more convenient. Mylan further objects to this Request in that it seeks documents or information that are unduly burdensome to locate or obtain, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Mylan also objects to the extent this Request seeks information predating Mylan's sales of VCMs in the United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process, which includes information regarding Mylan's FDA-approved labeling for VCMs. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 81: *All advertisements, and sales and marketing material for valsartan utilized from January 1, 2010 to the present, and charts setting forth the approval date, in use dates, and medium (i.e. website, sales document, marketing brochure).*

RESPONSE TO REQUEST NO. 81: Mylan incorporates, by reference, its Response to Request No. 31. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to individual Defendants, seeks documents outside the scope of issues in the present Actions, and requests the production of "all" documents. Mylan further objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because advertisements, as well as sales and marketing materials, are wholly unrelated to the issues in present Actions. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to marketing for Valsartan sold or distributed into the United States market. Mylan further objects to this Request in that it seeks documents or information that are not known,

are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record—including, for example, "charts"—that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request on the grounds that the term "advertisements" is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party's claim or defense nor proportional to the needs of each case, in that it purports to seek documents wholly unrelated to the issue in the present Actions. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Further, Plaintiffs' claims are based on recalls pursuant to FDA regulations. Therefore, documents regarding advertisements and sales and marketing materials for Valsartan API or Valsartan finished dose product advertised, sold, and/or marketed outside the U.S. market are not relevant to these Actions. Mylan further objects to the production of "marketing" materials until such time as Plaintiffs identify those documents upon which they or their physicians relied in deciding to prescribe, use, or purchase Mylan's VCMs. Without waiving the foregoing objections, Mylan states that it is presently not aware of any documents responsive to this Request.

REQUEST NO. 821: *Produce final and draft versions of all documents provided to consumers upon purchase of valsartan, (i.e. package inserts, patient brochures).*

RESPONSE TO REQUEST NO. 82: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to issues pertaining to alleged contamination of Valsartan API with NDEA and requests the production of "all" documents. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to labels on Valsartan sold or distributed into the United States market. Mylan also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. Mylan further objects to this Request as overbroad and unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to topics reasonably related to the alleged contamination of Valsartan API with NDMA

or NDEA and, instead, seeks documents relating to the labeling, sale, and marketing of Valsartan finished dose. Mylan further objects to this Request in that it seeks documents or information that are unduly burdensome to locate or obtain, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan states that it does not sell VCMs directly to patients. Further, Plaintiffs' claims are based on recalls pursuant to FDA regulations. Therefore, documents regarding labeling, selling, and/or marketing of Valsartan API or Valsartan finished dose product outside the U.S. market are not relevant to these Actions. Mylan also objects to the extent this Request seeks information predating Mylan's sales of VCMs in the United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence and ANDA files produced over the course of the core discovery process, which include information regarding Mylan's FDA-approved labeling for VCMs. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 83: *Produce all communications between you and any medical association concerning any adverse health effects that may or may not or be associated with valsartan.*

RESPONSE TO REQUEST NO. 83: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks documents outside the scope of issues in the present Actions and requests the production of "all" documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because sale and marketing materials are wholly unrelated to the issues in present Actions. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to materials provided to medical associations within the United States. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan also objects on the basis that the Request is overbroad, as Plaintiffs demand production of documents relating to "any adverse health effects," regardless of whether they relate to the injuries alleged in the Actions and irrespective of whether those "adverse health effects" are

associated with the presence of NDEA or NDMA. Moreover, the Request is ambiguous insofar as it seeks production of communications concerning “adverse health effects” that “may not be associated with valsartan,” which is open-ended and all-encompassing. “Medical association” is also vague, ambiguous, and subject to numerous interpretations. Mylan also objects to the extent this Request seeks information predating Mylan’s sale of VCMs in United States.

REQUEST NO. 84: *Produce documentation of any discussion or submission between Defendant and any medical association concerning any adverse events reported to be associated, regardless of causality, with valsartan.*

RESPONSE TO REQUEST NO. 84: Mylan incorporates, by reference, its Response to Request No. 83.

REQUEST NO. 85: *Produce all communications with financial analysts or investors concerning the role of valsartan in your financial or business prospects, including but not limited to any transcripts, presentations or documents concerning any analyst conference call, or business briefing.*

RESPONSE TO REQUEST NO. 85: Mylan objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to issues pertaining to alleged contamination of Valsartan API with NDEA and requests the production of “all” communications with unnamed “analysts or investors.” Mylan also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. Mylan further objects to this Request as irrelevant, overbroad and unduly burdensome, and not proportional to the needs of the Actions in that it is not limited to topics reasonably related to the alleged contamination of Valsartan API with NDMA or NDEA and, instead, seeks documents relating to “financial or business prospects.” Mylan further objects to this Request in that it seeks documents or information that are unduly burdensome to locate or obtain, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Mylan also objects to the extent this Request seeks information predating Mylan’s sales of VCMs in the United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the information available on the “Financials and Filings” webpage, <https://investor.mylan.com/financial-information/sec-filings>. To the extent Plaintiffs demand additional information, Mylan will engage in a meet and confer to

more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 86: *Produce all documents and communications evidencing questions from and responses to healthcare providers regarding the safety, quality, recall status, or purity of valsartan from June 1, 2018 to the present.*

RESPONSE TO REQUEST NO. 86: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that the Request seeks the production of “all” documents. The Request is also vague and ambiguous insofar as Plaintiffs demand production of documents “evidencing questions.” Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to communications with healthcare providers within the United States. Mylan further objects to this Request in that it seeks documents or information that are available in the public realm, are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request on the grounds that the term “healthcare providers” is vague, ambiguous, overbroad, and unduly burdensome, lacking in particularity, unreasonable and neither relevant to any party’s claim or defense nor proportional to the needs of each case, in that it purports to seek information from numerous unidentifiable entities based on a subjective assessment of whether or not the entity provides healthcare services. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to FDA’s public statements concerning the recalls of VCMs and the related investigation. To the extent Plaintiffs demand additional information, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 87: *Produce all documents reflecting public statements made by you regarding valsartan quality, purity, contamination, safety, or manufacturing process,, [sic]*

including but not limited to drafts and final versions of annual reports, press releases, and investor presentations.

RESPONSE TO REQUEST NO. 87: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to issues pertaining to alleged contamination of Valsartan API with NDEA and requests the production of “all” public statements which are, by definition, equally accessible to Plaintiffs. Mylan therefore also objects to this request to the extent it seeks documents or information that is available from another source that is more convenient. Mylan further objects to this Request as irrelevant, overbroad and unduly burdensome, and not proportional to the needs of the Actions. Mylan further objects to this Request in that it seeks documents or information that are unduly burdensome to locate or obtain, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Mylan also objects to the extent this Request seeks information predating Mylan’s sales of VCMs in the United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the information available on the “Financials and Filings” webpage, <https://investor.mylan.com/financial-information/sec-filings>. To the extent Plaintiffs demand additional information, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 88: *Produce all documents reflecting any communication between you and any consumers, medical professionals, healthcare insurers, PBMs, wholesale distributors, retail pharmacies, investors, analysts, or the media regarding valsartan.*

RESPONSE TO REQUEST NO. 88: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to issues pertaining to alleged contamination of Valsartan API with NDEA and requests the production of “all” documents reflecting “any” communication with a wide swath of persons and entities, irrespective of whether those

communications have anything to do with products, risks, or impurities at issue in the Actions. Mylan also objects to this request to the extent it seeks documents or information that is publicly available or otherwise available from another source that is more convenient. Mylan further objects to this Request as irrelevant, overbroad and unduly burdensome, and not proportional to the needs of the Actions. Mylan further objects to this Request in that it seeks documents or information that are unduly burdensome to locate or obtain, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Mylan also objects to the extent this Request seeks information predating Mylan's sales of VCMs in the United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the information available on the "Financials and Filings" webpage, <https://investor.mylan.com/financial-information/sec-filings>. Mylan also refers Plaintiffs to the FDA correspondence produced during the core discovery process, which includes information regarding Mylan's notices of recall concerning VCMs. To the extent Plaintiffs demand additional information, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 89: *Produce all documents with regard to any policy, procedure, or marketing strategy you used to market, advertise, promote, and/or sell valsartan from January 1, 2010 to the present.*

RESPONSE TO REQUEST NO. 89: Mylan incorporates, by reference, its Response to Request Nos. 31 and 81. Mylan objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks documents outside the scope of issues in the present Actions and requests the production of "all" documents in any way relating to "any" unspecified "policy, procedure, or marketing strategy" concerning "valsartan." Mylan further objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because advertisements, as well as sales and marketing materials, are wholly unrelated to the issues in present Actions. Mylan further objects to this

Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to marketing for Valsartan sold or distributed into the United States market. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Further, Plaintiffs' claims are based on recalls pursuant to FDA regulations. Therefore, documents regarding advertisements and sales and marketing materials for Valsartan API or Valsartan finished dose product advertised, sold, and/or marketed outside the U.S. market are not relevant to these Actions. Mylan further objects to the production of "marketing" materials until such time as Plaintiffs identify those documents upon which they or their physicians relied in deciding to prescribe, use, or purchase Mylan's VCMs. Mylan also objects to the extent the requested materials are publicly available. Notwithstanding the above, and subject to the objections asserted herein, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 90: *Produce all documents and communications with the Centers for Disease Control (CDC), National Institutes of Health, World Health Organization, U.S. Drug Enforcement Agency, U.S. Department of Justice, or U.S. Attorney General relating to valsartan contamination.*

RESPONSE TO REQUEST NO. 90: Mylan objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to issues pertaining to alleged contamination of Valsartan API with NDEA and requests the production of "all" documents reflecting communication with a wide swath of persons and entities, irrespective of whether those communications have anything to do with products, risks, or impurities at issue in the Actions. Mylan further objects to the extent this Request seeks information relating to VCMs marketed outside of the United States. Mylan also objects insofar as Plaintiffs seek information predating Mylan's sale of VCMs in the United States. Mylan further objects to this Request on the grounds that the term "valsartan" is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request to the

extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 91: *Produce all documents relating to the investigative subpoenas and subsequent investigation from the United States Department of Justice, United States Senate, and/or any other federal or state entity, relating to valsartan contamination, including, but not limited to, the information requested and produced by defendant, as well as communications between the defendant and the federal or state entity which served the subpoenas and/or conducted the investigation.*

RESPONSE TO REQUEST NO. 91: Mylan objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to issues pertaining to alleged contamination of Valsartan API with NDEA and requests the production of “all” documents reflecting communication with a wide swath of persons and entities, irrespective of whether those communications have anything to do with products, risks, or impurities at issue in the Actions. Mylan further objects to the extent this Request seeks information relating to VCMs marketed outside of the United States. Mylan also objects insofar as Plaintiffs seek information predating Mylan’s sale of VCMs in the United States. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan states that it is not presently aware of any materials responsive to this Request.

REQUEST NO. 92: *Produce all documents relating, referring to or embodying any discussion or submission between defendant and any state government regulatory agency or any state medical society concerning valsartan, including agreements related to reimbursement for valsartan.*

RESPONSE TO REQUEST NO. 92: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88). Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of any “discussion or submission” between Mylan and

“any” state agency or medical society. This Request does not define with sufficient particularity the materials sought by Plaintiffs. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to reimbursements issued in connection with the recall of VCMs or the potential presence of NDEA. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the recalls, products, and impurities at issue in the Actions and requests the production of “all” documents relating to the “reimbursement for valsartan,” irrespective of whether the refund has any bearing on this litigation. Mylan further objects to this Request in that it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business, or otherwise would require an unreasonable search of Mylan’s documents. Mylan also objects on the basis that the Request seeks information predating Mylan’s sales of VCMs in the United States. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that it seeks information predating its sale of VCMs in the United States. Mylan objects to this Request in that the term “state government regulatory agency or any state medical society” is vague and ambiguous. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence produced over the course of the core discovery process, which includes information regarding the issuance of refunds in connection with Mylan’s recalls of VCMs. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

XV. SALE AND DISTRIBUTION

REQUEST NO. 93: *Produce complete documentation setting forth and/or demonstrating the complete supply and distribution chain for valsartan purchased, sold, or distributed by you, from the manufacture of the API through the final sale to the consumer.*

RESPONSE TO REQUEST NO. 93: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan API and VCMs purchased, sold, or distributed into the United States market, and it requests the production of “complete documentation.” Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks documents and information either already produced through core discovery or publicly available. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek documents “demonstrating” the supply chain and therefore does not identify specific documents with reasonable particularity. By way of further answer, Mylan states as follows: Mylan does not have documentation reflecting the manufacture and distribution of VCMs at all levels of the supply chain through the final sale from a pharmacy to a customer. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the FDA correspondence and other information produced over the course of the core discovery process, which includes information regarding Mylan’s customer and consignee lists. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 94: *Produce all documents relating to the sale and distribution of valsartan that reflect NDC, batch number, and lot number.*

RESPONSE TO REQUEST NO. 94: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan

sold or distributed in the United States market, and it requests the production of “all” documents. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as “all documents relating to” the sale of Valsartan does not identify any particular set of documents and is duplicative of other Requests, including Requests No. 93, 95, and 99–111. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks documents and information either already produced through core discovery or publicly available. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, FDA correspondence, and other information produced over the course of the core discovery process, which includes information regarding the labeling for Mylan’s VCMs (and, by extension, NDCs), Mylan’s customer and consignee lists, and lot and batch information. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 95: *Produce documents sufficient to show all sales of valsartan to wholesalers, distributors, retailers, and consumers, including the total net sales, total number of pills and/or units sold, unit price, unit cost, profit margin, and market share by state or territory.*

RESPONSE TO REQUEST NO. 95: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to sales of Valsartan API or Valsartan finished dose in the United States market, and it requests the production of documentation related to “all” sales. Mylan further objects to this

Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because Mylan's market share and net sales, and the unit price, unit cost, and profit margin for Valsartan API or finished dose at the manufacturer level, are not relevant to any potential damages. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek "documents sufficient to show" all sales and therefore does not identify specific documents with reasonable particularity. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, FDA correspondence, and other information produced over the course of the core discovery process, which includes information regarding Mylan's customer and consignee lists and lot and batch information. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO 96: *Produce all documentation relating to the due diligence performed (or meant to be performed) in selecting an API or finished dose manufacturer from which you purchased valsartan, including but not limited to policies and procedures.*

RESPONSE TO REQUEST NO. 96: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the purchase or sale of Valsartan API or Valsartan finished dose in the United States market, and it requests the production of "all" documents. Mylan further objects to this Request as overbroad, unduly burdensome, not relevant to any party's claims or defenses, and not proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDMA or NDEA in Valsartan. Mylan also objects on the basis that this Request, referencing "due diligence performed

(or meant to be performed),” does not identify the specific documents sought with reasonable particularity. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody, or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Mylan also objects to the extent this Request demands production of information predating Mylan’s sale of VCMs in the United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, FDA correspondence, and other information produced over the course of the core discovery process. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 97: *Produce all documents and communications from any API manufacturer or finished dose manufacturer with regard to the manufacturing process, ingredients, quality, purity, or contamination relating to valsartan.*

RESPONSE TO REQUEST NO. 97: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the purchase or sale of Valsartan API and Valsartan finished dose in the United States market and requests the production of “all documents and communications” on a wide array of topics irrespective of whether they bear any relation to the issues relevant to the Actions. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions because it seeks information about all aspects of the API and finished dose manufacturing processes and is not limited to the specific step in the Valsartan API manufacturing process that allegedly generated NDMA or NDEA. Mylan further objects to this Request as overbroad, unduly burdensome, not relevant to any party’s claims or defenses, and not proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDMA or NDEA in Valsartan. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain,

are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the DMF, ANDA files, FDA correspondence, and other information produced over the course of the core discovery process. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 98: *Produce all documents relating to your decision to purchase valsartan from any API or finished dose manufacturer, including documents you reviewed or relied on to make those decisions.*

RESPONSE TO REQUEST NO. 98: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to purchase of Valsartan for sale or distribution in the United States market and requests the production of "all" documents. Mylan further objects to this Request as overbroad, unduly burdensome, not relevant to any party's claims or defenses, and not proportional to the needs of the Actions, in that Plaintiffs do not allege that the finished dose manufacturing process had any effect on the presence of NDMA or NDEA in Valsartan. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as "all documents related to your decision to purchase valsartan" does not identify any particular set of documents and is duplicative of other Requests, including Request No. 96. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Mylan also objects to the extent this Request demands production of information predating Mylan's sale of VCMs in the United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, FDA correspondence, and other information produced over the course of the core discovery process. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet

and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

XVI. IDENTIFICATION OF PURCHASERS

REQUEST NO. 99: *Produce documents sufficient to identify all persons and entities (including consumers and TPP entities) who purchased, reimbursed, or paid or otherwise compensated you for valsartan you manufactured, sold or distributed in the United States. If available, produce documents sufficient to show these individuals' or entities' names, last known mailing addresses and email addresses, last known telephone numbers, date(s) of purchase, NDC Code(s), Batch Number(s), and Lot Numbers.*

RESPONSE TO REQUEST NO. 99: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests an unreasonable level of detail and requests the production of “all” documents. Mylan further objects to this Request as it seeks information that is not known, is unduly burdensome to locate or obtain, is outside Mylan’s possession, custody or control, is not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan’s documents. Mylan also objects to the extent the information sought by Plaintiffs is already in their possession, custody, and control or is equally accessible to Plaintiffs. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek “documents sufficient to show” purchasers and therefore does not identify specific documents with reasonable particularity. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, FDA correspondence, and other information produced over the course of the core discovery process, which includes information regarding Mylan’s customer and consignee lists and lot and batch information. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 100: *Produce all documents and communications between or among you and any named plaintiff, including consumers and/or TPP entities, including but not limited to MSP Recovery Services (including its assignors, Summacare, Emblem, and Connecticare) and Maine Automobile Dealers Association.*

RESPONSE TO REQUEST NO. 100: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to communications related to Valsartan or the recall of VCMs and requests the production of “all” documents and communications. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests documents and communications that are in Plaintiffs’ possession, custody or control.

XVII. SALES AND PRICING

REQUEST NO. 101: *Produce all documents relating to valsartan sales you made in the United States to any purchaser (including, but not limited to, wholesalers, distributors, retailers and retail consumers), including documents that reflect total gross sales, total net sales, total number of units sold, unit price (gross and net), unit cost, cost of goods sold, profit margin, NDC, batch number, and lot number, on an annual basis, by, defendant, state, territory or the District of Colombia.*

RESPONSE TO REQUEST NO. 101: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks information about all levels of the supply chain and requests “all” documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions, in that gross sales, net sales, unit price, unit cost, cost of goods sold, and profit margin are not relevant to any potential damages. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan’s documents. Mylan also objects to the extent Plaintiffs seek information in their possession, custody, or control or equally accessible to them. Notwithstanding the above, and

subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, FDA correspondence, and other information produced over the course of the core discovery process, which includes information regarding Mylan's customer and consignee lists and lot and batch information. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 102: *Produce all documents and communications relating to your market share for valsartan, or competition for market share for valsartan, in the United States.*

RESPONSE TO REQUEST NO. 102: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because market share and competition are wholly unrelated to the issues in present Actions. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Mylan also objects to the extent Plaintiffs seek information in their possession, custody, or control or equally accessible to them. Mylan further objects to this Request as vague and ambiguous, insofar as Plaintiffs do not describe with reasonable particularity the documents they seek with regard to "competition for market share."

REQUEST NO. 103: *All documents and communications relating to negotiations over price and terms of sale or distribution between any defendant and any purchaser or re-seller of valsartan.*

RESPONSE TO REQUEST NO. 103: Mylan objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because pricing negotiations and competition are wholly unrelated to the issues in present Actions. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to a particular Defendant or Valsartan sold or distributed into the United States market. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of

business or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine.

REQUEST NO. 104: *Produce all documents and communications relating to any agreements or arrangements between you and any TPP entity (or any person acting on behalf of a TPP entity) that did, could, or may affect the quantity or price of valsartan purchased (including e.g., rebate agreements, etc.).*

RESPONSE TO REQUEST NO. 104: Mylan objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because pricing arrangements are wholly unrelated to the issues in present Actions. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to Valsartan sold or distributed into the United States market. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Mylan further objects to this request as overbroad, unduly burdensome, and not proportional to the needs of the Actions to the extent it requests documents that are in the possession of the Plaintiff TPP entities. Mylan further objects to this Request as vague and ambiguous, insofar as Plaintiffs do not describe with reasonable particularity the documents they seek with regard to "agreements or arrangements . . . that did, could, or may affect the quantity or price of valsartan."

REQUEST NO. 105: *Produce all documents relating to any arrangements between you and any other person or entity that did, could, or may affect the quantity or price of valsartan purchased, including but not limited to rebate agreements.*

RESPONSE TO REQUEST NO. 105: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents. Mylan objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because pricing arrangements are wholly unrelated to the issues in present Actions. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome

to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to arrangements for sale of Valsartan in the United States market. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, because Plaintiffs do not define what arrangements "did, could, or may affect the quantity or price of valsartan purchased." Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Mylan also objects to the extent the information sought in this Request is already in Plaintiffs' possession, custody, or control.

REQUEST NO. 106: *Documents sufficient to identify all retailers and/or sellers (including but not limited to, retail pharmacies, mail order pharmacies) who have offered valsartan for sale in the United States and territories from January 1, 2010 to the present, including but not limited to the name, location, and sales volume for each such retailer, as well as the relevant NDC, Batch Numbers, and Lot Numbers for each seller or retailer, where available.*

RESPONSE TO REQUEST NO. 106: Mylan objects to those parts of this Request which are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Mylan simply is not in possession of information "sufficient to identify all retailers and/or sellers (including but not limited to, retail pharmacies, mail order pharmacies) who have offered valsartan for sale in the United States and territories," let alone at the level of detail demanded by Plaintiffs. Mylan also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek "documents sufficient to identify" all retailers and/or sellers and therefore does not identify specific documents with reasonable particularity. Mylan

also objects to the extent Plaintiffs demand information predating Mylan's sale of VCMs in United States. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, FDA correspondence, and other information produced over the course of the core discovery process, which includes information regarding Mylan's customer and consignee lists and lot and batch information.

REQUEST NO. 107: *For each month from January 1, 2010 to the present, produce all documents relating to your actual and projected valsartan sales, including:*

- a. List price;*
- b. Average marginal price;*
- c. Average wholesale price;*
- d. Wholesale acquisition cost;*
- e. Direct price;*
- f. Average discount off of wholesale price or wholesale acquisition cost;*
- g. Price under Medicare program;*
- h. Price under Medicaid program;*
- i. Maximum allowable price;*
- j. Average manufacturing price (AMP) as defined by, and reported to, the Centers for Medicare and Medicaid Services;*
- k. Best price, as defined by, and reported to, the Centers for Medicare and Medicaid Services;*
- l. Net revenue;*
- m. Gross sales;*
- n. Net sales;*
- o. Units;*
- p. Gross shipments;*
- q. All measures of margin, income, earnings, and profits;*
- r. Unit of volumes sold;*
- s. Unit of volumes sold net of returns;*
- t. Total product contribution;*
- u. All costs and expenses attributable to the product;*
- v. Sales and distribution cost;*
- w. Cost of goods sold;*
- x. Manufacturing costs;*
- y. Marketing, advertising, promotional, and sales expenses;*
- z. Depreciable and capital improvements;*
- aa. Regulatory compliance;*
- bb. Short-run average variable costs;*
- cc. Long-run average variable costs;*
- dd. Fixed costs;*
- ee. Materials cost;*
- ff. Labor cost;*
- gg. Marginal cost;*
- hh. Rebates, discounts, vouchers, or other product promotions, returns, or charge-backs; and*

ii. *Coupons or co-pay cards.*

RESPONSE TO REQUEST NO. 107: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests an unreasonable level of detail and requests the production of “all” documents. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions because the categories of information related to, for example, costs are not relevant to any potential damages. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the United States market. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek “documents relating to” actual and projected sales therefore does not identify specific documents with reasonable particularity. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Notwithstanding the above, and subject to the objections asserted herein, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 108: *Documents and communications sufficient to identify every entity that purchased, reimbursed, or compensated you for valsartan from you from January 1, 2010 to the present.*

RESPONSE TO REQUEST NO. 108: Mylan objects to those parts of this Request that are duplicative of the core discovery production previously ordered by the Court. (Dkt. 88.) Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to sales of Valsartan in the United States market, and it requests the production of documentation related to “every” entity. Mylan further objects to this

Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek "documents sufficient to show" all entities and therefore does not identify specific documents with reasonable particularity. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan also objects to the extent Plaintiffs seek information in their possession, custody, or control or equally accessible to them. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, FDA correspondence, and other information produced over the course of the core discovery process, which includes information regarding Mylan's customer and consignee lists. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 109: *Produce all documents relating to contracts for the sale of valsartan from January 1, 2010 to the present including (a) contracts with direct purchasers; (b) contracts that provide that the purchaser will take delivery of valsartan from another entity (such as a wholesaler); and (c) contracts concerning or regarding the payment of chargebacks.*

RESPONSE TO REQUEST NO. 109: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to contracts for sale of Valsartan in the United States market and it requests the production of "all" documents. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because pricing at the manufacturer level is not relevant to the issues in these Actions. Mylan

further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, in that it purports to seek “documents relating to” contracts therefore does not identify specific documents with reasonable particularity. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO. 110: *Produce complete documentation of the date, manufacturing source, quantity, and recipient of all samples of valsartan provided by defendant.*

RESPONSE TO REQUEST NO. 110: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the United States market and it requests the production of “complete” documentation. Mylan further objects to this Request on the grounds that the term “valsartan” is vague, ambiguous, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as it does not distinguish between Valsartan API and Valsartan finished dose. It is also unclear what is meant by “sample.” Mylan also objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions in that it seeks information about Valsartan “samples” and is not limited to the NDMA or NDEA impurities at issue in these Actions. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan further objects to this Request as vague, ambiguous, overbroad and unduly burdensome,

lacking in particularity, and unreasonable, in that it purports to seek “complete documentation of” samples and therefore does not identify specific documents with reasonable particularity. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, FDA correspondence, and other information produced over the course of the core discovery process, which includes information regarding Mylan’s customer and consignee lists and lot and batch information. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

REQUEST NO 111: *Produce all electronic data in tab-delimited, comma-delimited, or semicolon-delimited ASCII flat text or similar electronic format from January 1, 2010 to the present sufficient to identify all sales of valsartan to purchasers in transaction-by-transaction format, as follows:*

a. *All direct sales/invoice transactions (as well as any discounts or any other price adjustments or offsets contained in the transaction data) including the following fields: (i) price or dollar amount, (ii) source of the transaction price, (iii) number of units sold, (iv) number of units returned or otherwise affected by the transaction, (v) unit of measure, (vi) date of transaction, (vii) information sufficient to identify the type of transaction (e.g., a sale, a return, a discount, etc.), (viii) NDC, (ix) UPC, (x) SKU, (xi) product description, (xii) product form, (xiii) strength, (xiv) package size in extended units per package, (xv) customer name, (xvi) customer number, (xvii) customer address, (xviii) customer class of trade code and the description of that code (all such customer information being provided for both the bill-to and ship-to customer), and (xix) the customer’s parent company (if the data identifies a subsidiary, corporate affiliate, division, satellite office, distribution center, warehouse, or the like).*

b. *All data concerning chargebacks, rebates, discounts, and other consideration given or accrued relating to valsartan, including the following fields: (i) each transaction, including the date thereof; (ii) the name and address of, and all unique codes or identifiers for, the person, firm corporation, or other business entity whom you paid, or on whose behalf you accrued, the chargeback, rebate, discount and/or other consideration; (iii) the name and address of, and all unique codes or identifiers for, the persons, firms, corporations, or other business entities that made the purchases in respect of which you paid or accrued the chargeback, rebate, discount, or other consideration; (iv) the sales, or groups of sales, upon which the rebate, discount, or other consideration is based, including: (aa) the number of units of the particular product sold, by package size, SKU, UPC, NDC, and any and all other unique codes or other identifiers*

for each sale or other transaction; (bb) the bill-to customer; (cc) the ship-to customer; (dd) the dates of the sales, or group of sales; (ee) the invoice amount in dollars for the sales or group of sales; (ff) the amount of the chargeback, rebate, discount, or other consideration paid or accrued; and (gg) the contract, agreement, or other basis upon which the chargeback, rebate, discount, or other consideration is calculated.

c. All administrative fee transactions relating to valsartan, including: (i) fee amount paid, (ii) date of payment, (iii) date or date range of sales concerning the fee that was paid, (iv) information sufficient to identify the type of administrative fee (if applicable), (v) customer name, (vi) customer number, (vii) customer address, and (viii) customer class of trade code and the description of that code;

d. For all other transaction types not reflected in (a) through (c) above, produce all documents relating to any other paid or accrued discounts, rebates, chargebacks, billbacks, unit adjustments, price adjustments, shelf-stock price adjustments, returns, third-party returns, error corrections, free goods, nominally-priced goods, whether created or maintained daily, monthly, quarterly, or at some other periodicity, with regard to valsartan.

e. The complete documentation for all items above (a through d) including (i) lookup tables, (ii) data dictionaries, (iii) lists of fields, (iv) descriptions of information contained in those fields (e.g., field lengths, formats, etc.), and (v) descriptions of any codes used in any fields (such as class of trade designations, etc.), including but not limited to (aa) a separate product list, including NDC, SKU, UPC, product description, and package size; (bb) a separate table that lists, for each “bill-to customer” and “shipto customer,” the customer number, parent customer number, customer group number, customer identity, contact information, address, and class of trade (e.g., SIC code); (cc) a separate table listing and defining each transaction code, abbreviation, or other field or entry code, and indicating (1) whether quantity values for each transaction type should be included in calculating net quantity sold, or should be ignored because they do not affect net quantity sold and (2) how negative unit and dollar values should be treated in calculating net quantities and dollar amounts; (dd) all data sets and calculations used to (1) determine accrued rebates and/or chargebacks and/or (2) periodically reconcile accrued rebates and/or chargebacks with actual rebates and/or chargebacks; (vi) return and/or exchange policies; and (vii) payment terms.

RESPONSE TO REQUEST NO. 111: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the United States market and requests the production of “all” documents. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan’s possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan’s documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party’s claims or defenses nor proportional to the needs of the Actions in that it seeks information that is not limited to the NDMA or NDEA impurities at issue in these Actions. Mylan further objects to this

Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions because the categories of information related to, for example, costs are not relevant to any potential damages. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan refers Plaintiffs to the ANDA files, FDA correspondence, and other information produced over the course of the core discovery process, which includes information regarding Mylan's customer and consignee lists and lot and batch information. To the extent Plaintiffs demand additional information in response to this Request, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

XVIII. AVAILABLE DATA SOURCES

REQUEST NO. 112: *Produce all documents relating to all IMS, Verispan, MediSpan, Scott-Levin, PriceCheck, ImpactRx, First DataBank, or other pharmaceutical industry data products purchased and or subscribed to or available to you regarding valsartan.*

RESPONSE TO REQUEST NO. 112: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the United States market and requests the production of "all" documents. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it seeks information that is not

limited to the NDMA or NDEA impurities at issue in these Actions. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012.

REQUEST NO. 113: *Produce all data or reports generated by IMS, CMS, or Verispan, or any comparable third party person or entity (including, but not limited to, Medi-Span, ImpactRx, and First DataBank), in whatever format it was received, relating to the sale, prescription, marketing, promotion, or detailing of valsartan from date of launch to the present for valsartan, including:*

- a. IMS National Prescription Audit data, including TRx, NRx, extended units, retail sales dollars and retail sales price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.*
- b. IMS National Sales Perspective data, including total units, extended units, total sales dollars, and price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.*
- c. CMS national Health Expenditures and Drug Utilization data, including TRx, NRx, Medicaid percentage paid, extended units, retail sales dollars, and retail sales price, with regard to valsartan.*
- d. Verispan Vector One National (VONA) data, including TRx, NRx, extended units, retail sales dollars, and retail sales price, with regard to valsartan. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.*

RESPONSE TO REQUEST NO. 113: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the United States market and requests the production of "all" documents. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it seeks information that is not limited to the NDMA or NDEA impurities at issue in these Actions. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not

exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34. Mylan also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions to the extent it seeks documents predating September 21, 2012. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney-client privilege or attorney work-product doctrine

REQUEST NO. 114: *Produce all documents relating to any coupon or co-pay assistance you made available to consumers for valsartan.*

RESPONSE TO REQUEST NO. 114: Mylan objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it requests the production of "all" documents related to "any" coupon or co-pay assistance. Mylan further objects to this Request as it seeks documents or information that are not known, are unduly burdensome to locate or obtain, are outside Mylan's possession, custody or control, are not kept in the ordinary course of business or otherwise would require an unreasonable search of Mylan's documents. Mylan further objects to this Request as it seeks documents that are neither relevant to any party's claims or defenses nor proportional to the needs of the Actions in that it seeks information that is not limited to the NDMA or NDEA impurities at issue in these Actions. Mylan also objects to this request to the extent it seeks documents or information that is publicly available or available from another source that is more convenient. Mylan further objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it is not limited to the United States market. Mylan further objects to those parts of this Request that purport to obligate Mylan to create a documentary record that does not exist in the ordinary course of business, as it purports to impose burdens on Mylan beyond those authorized by Fed. R. Civ. P. 34.

XIX. DEFENDANT-SPECIFIC REQUESTS

A. To Mylan:

REQUEST NO. 115: *Produce all documents, communications, and filings associated with Mylan's ANDA 20473. This includes but is not limited to the initial ANDA submission, subsequent amendments to the ANDA submission, correspondence from the FDA regarding that ANDA submission, responses to correspondence from the FDA regarding that ANDA*

submission, and any and all supporting documentation filed with the FDA, including bioequivalence information, manufacturing information, and testing regarding ANDA 20473.

RESPONSE TO REQUEST NO. 115: Mylan objects to this Request as irrelevant, overbroad, unduly burdensome, and not proportional to the needs of the Actions. Initially, Mylan states that it is not the holder of “ANDA 20473.” Nevertheless, Mylan will assume Plaintiffs intended instead to refer to ANDA 204743 which, as noted, relates to generic Exforge HCTZ and remains pending before FDA. Mylan states that documents relating to ANDA 204743 are immaterial because it relates to a product which has never been marketed in United States and, therefore, could not possibly have been purchased or used by Plaintiffs. Moreover, issues of bioequivalence relate to finished dosage forms, and Plaintiffs do not allege that the manufacturing process for Valsartan finished dose caused the formation of NDEA. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Nonetheless, Mylan states that it has produced during core discovery its communications with FDA relating to the potential presence of NDMA or NDEA in Valsartan, the related recalls, and the subsequent investigation, irrespective of whether those communications related to ANDA 204743 or an approved application.

REQUEST NO. 116: *Produce all inspection documents, including any and all Form 483s, and EIRs, and correspondence from the FDA associated with Mylan’s Nashik facility, including but not limited to the September 2016 inspection and resulting warning letter and November 2018 inspection and warning letter.*

RESPONSE TO REQUEST NO. 116: Mylan objects to this Request on the basis that it is unduly burdensome, overly broad, and irrelevant. Mylan further objects on the basis that this Request seeks information predating September 21, 2012. Mylan also objects insofar as this Request seeks production of information unrelated to the manufacture of Valsartan API or VCMs. To the extent FDA may have issued, for example, a 483 concerning a product other than Valsartan API or VCMs, it is irrelevant to this litigation and production of such information is unduly burdensome. Mylan states further: This litigation centers upon Plaintiffs’ allegation that impurities arose during the process of manufacturing MLL’s Valsartan API. MLL, however, did not manufacture Valsartan API at its Nashik facility. Accordingly, this Request exceeds the scope of discovery permitted under the Federal Rules of Civil Procedure.

REQUEST NO. 117: *Produce all inspection documents, including any and all Form 483s, and EIRs, and correspondence from the FDA associated with Mylan’s Morgantown, WV*

facility, including but not limited to documents regarding inspections which occurred in November of 2016, March 2018, April 2018, resulting correspondence with the FDA regarding these inspections (including but not limited to, notes, presentations and documents created as a result of in person meetings with regulatory officials).

RESPONSE TO REQUEST NO. 117: Mylan objects to this Request on the basis that it is unduly burdensome, overly broad, and irrelevant. Mylan further objects on the basis that this Request seeks information predating September 21, 2012. Mylan also objects insofar as this Request seeks production of information unrelated to the manufacture of Valsartan API or VCMs. To the extent FDA may have issued, for example, a 483 concerning a product other than Valsartan API or VCMs, it is irrelevant to this litigation and production of such information is unduly burdensome. Mylan states further: This litigation centers upon Plaintiffs' allegation that impurities arose during the process of manufacturing MLL's Valsartan API. MPI, however, did not manufacture Valsartan API at its Morgantown facility. Accordingly, this Request exceeds the scope of discovery permitted under the Federal Rules of Civil Procedure.

REQUEST NO. 118: *Produce all due diligence documents associated with Mylan's acquisition of Matrix Pharmaceuticals.*

RESPONSE TO REQUEST NO. 118: Mylan objects to this Request on the basis that it is unduly burdensome, overly broad, and irrelevant, particularly insofar as Plaintiffs demand production of "all" documents of a particular description. Mylan further objects on the basis that this Request seeks information predating September 21, 2012. Mylan also objects insofar as this Request seeks production of information unrelated to the manufacture of Valsartan API or VCMs. By way of further response, Mylan states that it has not acquired an entity called "Matrix Pharmaceuticals." Instead, in 2007, Mylan Inc. indirectly acquired an interest in Matrix Laboratories Ltd., which changed its name to Mylan Laboratories Ltd. in 2011. Mylan did not begin marketing VCMs in United States until 2012. Simply put, "due diligence documents" concerning Matrix Laboratories Ltd. are wholly irrelevant to this litigation. Moreover, Mylan has already produced as part of core discovery MLL's DMF for Valsartan API and the ANDA files for the three VCMs marketed in United States. Thus, any "Matrix" documents that could possibly have some bearing on the issues raised in this litigation are already in Plaintiffs' possession.

REQUEST NO. 119: *Produce all documents and communications regarding your contract with Lantech Pharmaceuticals for the recovery and further use of any and all solvents used in valsartan manufacturing.*

RESPONSE TO REQUEST NO. 119: Mylan objects to this Request on the basis that it is unduly burdensome, overly broad, and irrelevant, particularly insofar as Plaintiffs demand production of “all” documents of a particular description. Mylan further objects on the basis that this Request seeks information predating September 21, 2012. Mylan also objects insofar as this Request seeks production of information regardless of whether it has any bearing on the alleged presence of NDEA in Valsartan API and irrespective of whether the information sought is in the public domain. Mylan further objects to this Request because it is not limited to product manufactured for use in the United States market. Mylan further objects to this Request to the extent that it calls for the disclosure of information protected by the attorney–client privilege or attorney work-product doctrine. Notwithstanding the above, and subject to the objections asserted herein, Mylan will engage in a meet and confer to more appropriately define the scope of this Request in a manner consistent with the Federal Rules of Civil Procedure and the needs of this litigation.

Dated: October 15, 2019

Respectfully submitted,

s/ Clem C. Trischler

Clem C. Trischler

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CERTIFICATE OF SERVICE

I certify that on the 15th day of October, 2019, I served the foregoing document on Plaintiffs’ Co-Lead and Liaison Counsel via electronic mail.

s/ Clem C. Trischler